

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA LP and
ASTRAZENECA AB,

Plaintiffs,

-vs-

BREATH LIMITED,

Defendant.

ASTRAZENECA LP and
ASTRAZENECA AB,

Plaintiffs,

-vs-

APOTEX, INC. and APOTEX CORP.,

Defendants.

Consolidated Civil Action
No. 08-1512 (RMB) (AMD)

ASTRAZENECA LP and
ASTRAZENECA, AB,

Plaintiffs,

-vs-

SANDOZ, INC.,

Defendant.

TRIAL.

THIS TRANSCRIPT IS
PARTIALLY SEALED

ASTRAZENECA LP and ASTRAZENECA
AB,

Plaintiffs

-vs-

WATSON LABORATORIES, INC.,

Defendant.

1
2
3 Mitchell H. Cohen United States Courthouse
4 One John F. Gerry Plaza
5 Camden, New Jersey 08101
6 November 17, 2014
7

8 **B E F O R E:**

THE HONORABLE RENÉE MARIE BUMB
UNITED STATES DISTRICT JUDGE

9
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SANDOZ, INC.**18****19****20****21****22****23****24** Certified as true and correct as required by Title 28,
U.S.C, Section 753.**25** /s/ Theodore M. Formaroli, CSR, CRR

United States District Court
Camden, New Jersey

1 THE DEPUTY CLERK: All rise.

2 THE COURT: Please be seated.

3 Good morning. Nice to see you all.

4 Okay, we're here for the continuation of the trial.

09:09AM 5 If there is any part that needs to be sealed, the parties will
6 let me know.

7 MR. ANTHONY: I will, your Honor. And I was going to
8 alert the court that there will be portions that we will need
9 to request the court to seal the courtroom. I'll do my very
09:09AM 10 best to alert the court to that in advance and then when we're
11 done with those portions also to inform the court of that.

12 THE COURT: Okay. Thank you.

13 MR. ANTHONY: Good morning, your Honor. Stephen
14 Anthony for AstraZeneca. We do have a slightly different cast
09:09AM 15 of characters at counsel table this morning. The court knows
16 Mr. Patel and Mr. Sipes, but we also have with us at counsel
17 table Christopher Carlton, who is a senior counsel for
18 AstraZeneca.

19 MR. CARLTON: Good morning.

09:09AM 20 THE COURT: Welcome. Nice to meet you.

21 MR. ANTHONY: Your Honor, AstraZeneca calls Paul
22 Hudson.

23 THE COURT: Okay.

24 (PAUL HUDSON, HAVING BEEN DULY SWORN AS A WITNESS TESTIFIED AS
09:10AM 25 FOLLOWS:)

1 (DIRECT EXAMINATION OF MR. HUDSON BY MR. ANTHONY)

2 THE DEPUTY CLERK: Can you please state and spell
3 your full name for the record.

4 THE WITNESS: Paul Hudson. P-A-U-L, H-U-D-S-O-N.

09:10AM 5 THE COURT: Good morning.

6 THE WITNESS: Good morning.

7 THE COURT: Please have a seat. Speak into the
8 microphone and keep your voice up. There is water there if
9 you need it.

09:10AM 10 THE WITNESS: Thank you.

11 THE COURT: Okay.

12 MR. ANTHONY: Your Honor, we do have notebooks of
13 exhibits to use on direct examination with Mr. Hudson. If we
14 could hand them to counsel and to the court and to the witness
09:10AM 15 at this time.

16 And I do want to alert the court and counsel to
17 one -- and the witness -- no one substitution in an exhibit
18 number. In the binder there is an exhibit D, as in defendant,
19 TX-784. What we will use instead is an identical document
09:11AM 20 that is PTX, that's Plaintiff's Trial Exhibit, 927, which is
21 in evidence.

22 THE COURT: 927.

23 MR. ANTHONY: And counsel for Breath & Watson
24 courteously alerted me that PTX-927 is already in evidence.

09:11AM 25 So as to avoid duplication, we're going to use PTX-927, which

—Hudson - Direct - Anthony—

1 is in the witness' binder but not in the court's binder.

2 THE COURT: Okay. Thank you.

3 BY MR. ANTHONY:

4 Q. Good morning, Mr. Hudson.

09:11AM 5 A. Good morning.

6 Q. Would you please tell the court where you work.

7 A. I work for AstraZeneca. I'm based in Wilmington,
8 Delaware.

09:11AM 9 Q. Could you describe to the court your educational
10 background.

11 A. I have a bachelor's degree in economics from Manchester
12 Metropolitan University and a post graduate diploma in
13 marketing.

14 Q. What is your position at AstraZeneca?

09:12AM 15 A. I'm the executive vice president for North America and
16 the president of the U. S. business.

17 Q. And by the president of the U. S. business, so you are
18 president of AstraZeneca U. S.?

19 A. That's correct, yes.

09:12AM 20 Q. How long have you held that position?

21 A. Since January 2013.

22 Q. What are your responsibilities?

23 A. So, I have several responsibilities. As executive vice
24 president for AstraZeneca I sit on the main executive team
09:12AM 25 reporting to the CEO and have a responsibility for the global

Hudson - Direct - Anthony

1 performance and management of AstraZeneca. As president of
2 the U. S. business, I'm responsible for the sales, marketing
3 and medical functions and the commercialization of our
4 pharmaceuticals and their promotion in the United States.

09:12AM 5 Q. How long have you worked at AstraZeneca overall?

6 A. I joined AstraZeneca in June 2006.

7 Q. And what were your positions at AstraZeneca previous to
8 your current position?

9 A. So in June 2006 I joined AstraZeneca to be the vice
09:13AM 10 president of primary care in the U. K. In 2008, I was asked
11 to become president of AstraZeneca in Spain, which I did for
12 three years. In 2011 I became president of AstraZeneca in
13 Japan. And in January 2013 I took this role.

14 Q. What business is AstraZeneca in?

09:13AM 15 A. We're a pure-play biopharmaceutical company. We're not a
16 diversified business, we're purely focused on large and small
17 molecules that are research, development and
18 commercialization.

19 Q. Can you describe to the court what is the entity

09:13AM 20 AstraZeneca PLC in relation to the two entities AstraZeneca LP
21 and AstraZeneca AB?

22 A. So, AstraZeneca, we're a public limited company in the
23 United Kingdom. AB is the -- is a Swedish expression, I can't
24 remember the exact meaning of that word, but more around the
09:14AM 25 intellectual property and where that is held. And an LP is a

—Hudson - Direct - Anthony—

1 limited partnership, it's another corporate term.

2 Q. And is the PLC the public limited company in the UK the
3 parent of those two other entities?

4 A. That's correct.

09:14AM 5 Q. So describe for the court what are AstraZeneca's most
6 important therapeutic areas?

7 A. Well, AstraZeneca has a clearly stated group of
8 therapeutic areas that we're focused on, principle respiratory
9 disease, both asthma and COPD, both mild, moderate and sever
09:14AM 10 asthma and COPD. We have cardiometabolic, so that's
11 cardiovascular disease. Lipid lowering. Acute coronary
12 syndrome, heart attacks, in other words. And also Type 2
13 diabetes. So Hb1C, or blood sugar lowering. And then
14 oncology. And we're focused in breast, ovarian and lung
09:15AM 15 principally. And there are other therapeutic areas, but they
16 are fundamentally the ones that we focus on as an
17 organization.

18 Q. Where are AstraZeneca's worldwide headquarters located?

19 A. Currently our corporate head office is in King Street in
09:15AM 20 London.

21 Q. And what about AstraZeneca's North America headquarters
22 where you work, where is that located?

23 A. In Wilmington, Delaware.

24 Q. And where are some of AstraZeneca key sites in the United
09:15AM 25 States?

—Hudson - Direct - Anthony—

09:16AM 1 A. So we have a large research facility in Gaithersburg,
2 Maryland where we do most of our large molecule work. We also
3 have an infection research center up in Waltham,
4 Massachusetts. And then we have a significant number of sites
5 across the United States, mainly manufacturing, and some R&D
6 in California.

7 Q. How many people does AstraZeneca employ worldwide?

8 A. A little over 50-51,000 employees.

09:16AM 9 Q. And within that how many people does AstraZeneca employee
10 within the United States?

11 A. Approximately 12,000 employees.

12 Q. And do you know how many approved medications AstraZeneca
13 sells in the United States?

14 A. 44 approved medicines.

09:16AM 15 Q. And do you have any ability to tell the court the
16 magnitude of the number of patients who are treated with
17 AstraZeneca drugs in the U. S. in a year?

18 A. We routinely do a calculation to try and workout exactly
19 how many patients we serve, and it's approximately 24 million
09:16AM 20 Americans benefit in some form or another from an AstraZeneca
21 medication in a given year.

22 Q. Thank you. Now, I'd like to turn to the product history
23 of Pulmicort Respules. When did AstraZeneca first introduce
24 Pulmicort Respules outside the United States?

09:17AM 25 A. In the mid to late nineties, I think.

—Hudson - Direct - Anthony—

1 Q. And do you recall when Pulmicort Respules started selling
2 within the United States?

3 A. The early two thousands.

4 Q. Let me now ask you to turn to in your binder the exhibit
09:17AM 5 that's marked as exhibit DTX- 2044.

6 A. Yes.

7 Q. And we also have it up on the screen, but it's in the
8 binder in front of you. Do you recognize the exhibit marked
9 DTX- 2024? Which is in evidence, your Honor.

09:17AM 10 A. Yes, I do.

11 Q. What is it?

12 A. It's the reporting of the expenses, the direct ground
13 expenses invested in Pulmicort Respules on a yearly basis
14 dating back to 2000.

09:17AM 15 Q. Where was that information retrieved from?

16 A. This information is taken from our business insight, a
17 function which takes its data from our SAP process, which is
18 sort of the brains behind all of the data collection from
19 invoice sales say and expenses incurred on promotional
09:18AM 20 medicines.

21 Q. Is SAP capital S-A-P?

22 A. Sorry. Yes, that is correct.

23 Q. Is that essentially a system for collecting and recording
24 business information?

09:18AM 25 A. That is correct.

—Hudson - Direct - Anthony—

1 Q. And do you rely on information from what you refer to as
2 the business insight system to make decisions in your job?

3 A. Yes, I do.

4 Q. In preparing for testifying at this trial, did you take

09:18AM 5 steps to check the accuracy of the information in DTX- 2044 in
6 evidence?

7 A. Yes, I did.

8 Q. And what did you determine?

9 A. I determined that these numbers were accurate.

09:18AM 10 Q. Let me direct your attention to the second page of DTX-

11 2044 where it's headed AstraZeneca U. S. Pulmicort Respules

12 and it says dollars in millions of dollars. Do you see the

13 headings for the years 2000 to 2014 at the top there?

14 A. That's correct.

09:19AM 15 Q. And directing your attention to the last line on that

16 page where it says sales units 30 pack in thousands. What

17 does that line of numbers tell you, that last line which says

18 sales units?

19 A. That is the volume of units that are produced and are

09:19AM 20 used to calculate also the net sales.

21 Q. And if you added up all those numbers across in that

22 line, does that add up to 44 million packages of 30 individual

23 respules?

24 A. That is my understanding, yes.

09:19AM 25 Q. Okay. And the line just above it where it says net sales

—Hudson - Direct - Anthony—

1 and then it begins with the Number 35 in the year 2000, is
2 that the net sales in U. S. dollars in millions?

3 A. That's correct.

4 Q. And if I were to run and add up all those lines across
09:20AM 5 horizontally on that second to the bottom line, would I come
6 up with a number a little more than 5.6 billion dollars?

7 A. You would, yes.

8 Q. Let's look at, for example, the last full year that's
9 included, 2013. So what does this tell you about the net
09:20AM 10 sales in U. S. dollars in millions of dollars for Pulmicort
11 Respules for 2013?

12 A. Well, it just -- it gives us the product sales and then,
13 of course, we deduct returns, discounts, allowances, which
14 gives us a net sales value or, indeed, profit.

09:20AM 15 Q. Briefly can you explain what returns, discounts and
16 allowances are?

17 A. In its simplest form, returned are stock, for example,
18 that is past its expiration date that is returned. So that
19 would be a negative against this number. Discounts are
09:21AM 20 discounts paid as part of our normal rebating process. And
21 allowances are part of the distribution agreement with those
22 who distribute.

23 Q. So if I look at that column that you've been testifying
24 about, would that tell me that net sales for Pulmicort
09:21AM 25 Respules in the U. S. in 2013 was \$126 million?

—Hudson - Direct - Anthony—

1 A. That's correct, yes.

2 Q. Is there a licensed generic version of Pulmicort Respules
3 in the U. S.?

4 A. Yes, there is.

09:21AM 5 Q. And who sells that?

6 A. Teva.

7 Q. Do you recall approximately when Teva started selling
8 that licensed generic?

9 A. 2009.

09:21AM 10 MR. ANTHONY: At this time, your Honor, my next
11 series of questions are going to address the royalties issues
12 and so this would be the appropriate time, if the court
13 please, to seal the courtroom.

14 THE COURT: All right. Is there anybody who is not
09:22AM 15 covered by my confidentiality order in the courtroom?

16 Sir, would you mind exiting the courtroom? I'm going
17 to seal this portion of the proceeding for a moment.

18 MR. LEVY: Your Honor, there is a numbering of people
19 in the courtroom I recognize. And I'm actually Teva's lawyer.
09:22AM 20 I'm not under the protective order in this case, but Mr. Sipes
21 and Mr. Basil and Mr. Rakoczy is here --

22 THE COURT: Just tell me your name, sir.

23 MR. LEVY: Ira Levy.

24 THE COURT: Any objection to Mr. Levy being present
09:22AM 25 in the courtroom?

—Hudson - Direct - Anthony—

1 MR. ANTHONY: AstraZeneca has no objection.

2 MR. SIPES: We have no objection, your Honor.

3 THE COURT: What about the defendants?

4 MR. BASILE: I don't have a problem if we're talking
09:22AM 5 about AstraZeneca's information, AstraZeneca's family, but to
6 the extent they're getting into any of the defendants'
7 information, then we would want the courtroom sealed.

8 THE COURT: Yes. If this is dealing with -- is it
9 the same for you, Ms. Brody, Mr. Rakoczy?

09:22AM 10 MS. BRODY: Yes, your Honor.

11 THE COURT: Not Mr. Rakoczy. Mr. Gracey --

12 MR. GRACEY: Yes, your Honor.

13 THE COURT: -- Taras --

14 MR. GRACEY: Yes, your Honor.

09:22AM 15 MR. ANTHONY: Understood, your Honor.

16 MR. LEVY: Levy, your Honor.

17 THE COURT: -- Gracey.

18 (Laughter.)

19 THE COURT: No, I know --

09:23AM 20 MR. GRACEY: It's been a while.

21 THE COURT: Yes. Any objection by the three of you
22 to Mr. Levy being here, as long as it deals with Teva's
23 information?

24 MS. BRODY: Not from Breath & Watson, your Honor.

09:23AM 25 THE COURT: Okay.

Hudson - Direct - Anthony

1 MR. LEVY: Thank you, your Honor.

2 THE COURT: And then, AstraZeneca, you have no
3 objection?

4 MR. SIPES: No objection, your Honor.

09:23AM 5 THE COURT: All right. So, Mr. Anthony, if you get
6 into any information dealing with the defendants, then Mr.
7 Levy will have to exit the courtroom.

8 MR. ANTHONY: I agree. And I understand that, your
9 Honor. I don't anticipate that happening with this witness.

09:23AM 10 THE COURT: Anyone else here who is not subject to
11 the confidentiality order?

12 (No response.)

13 THE COURT: Okay.

14 (The courtroom was sealed by order of the court.)

09:23AM 15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

09:23AM 20 [REDACTED]

21 [REDACTED]

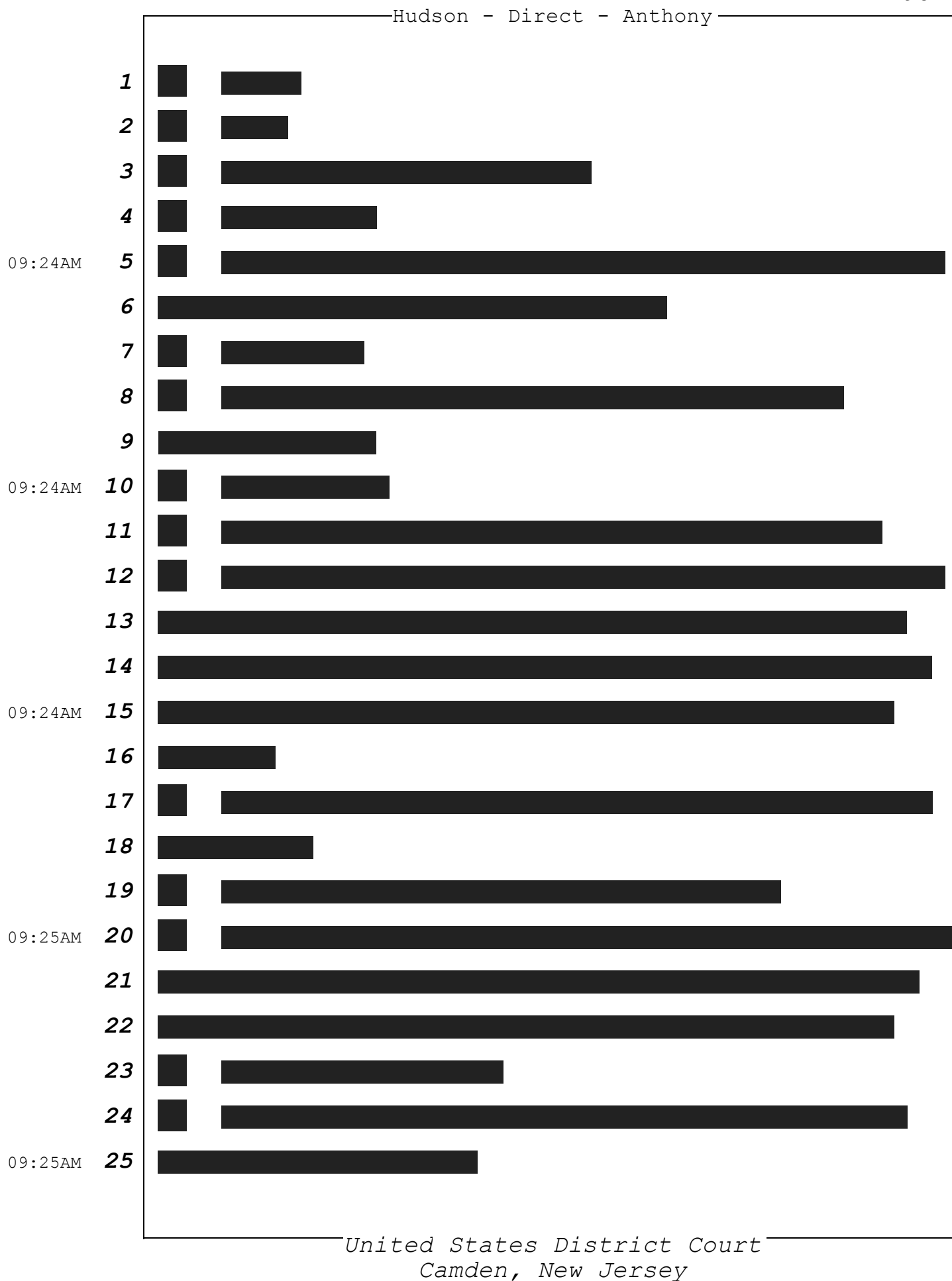
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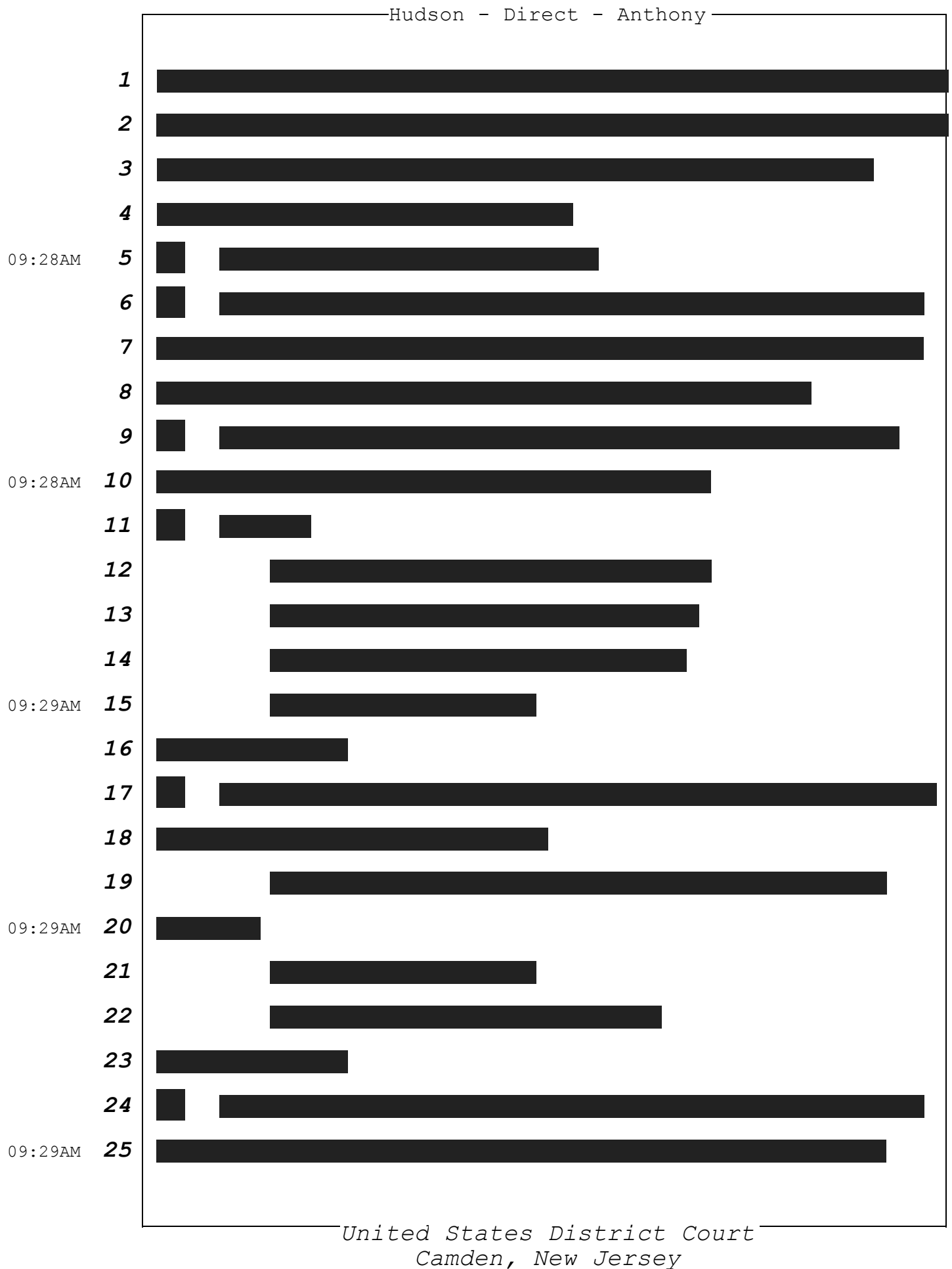
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United States District Court
Camden, New Jersey

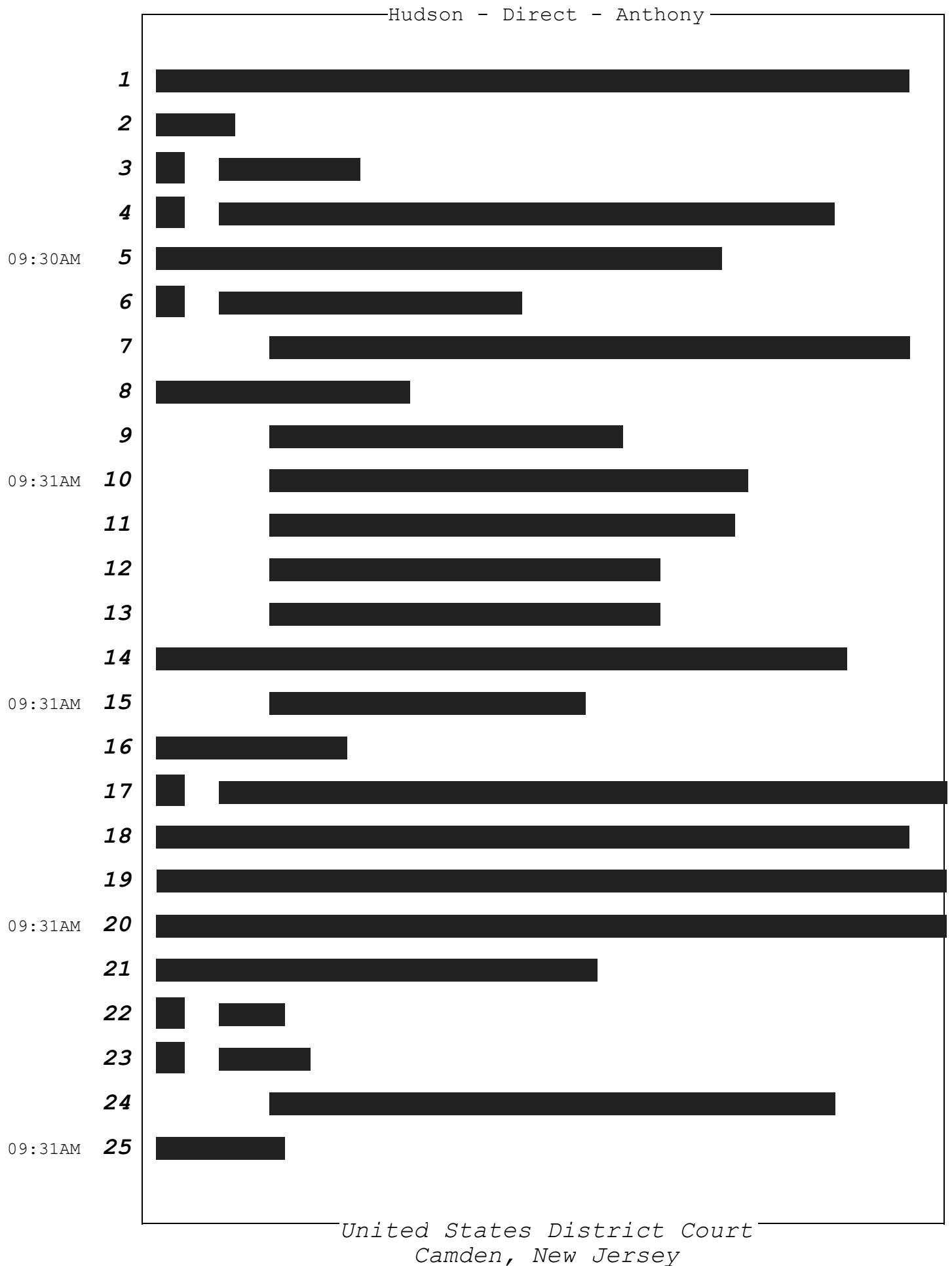




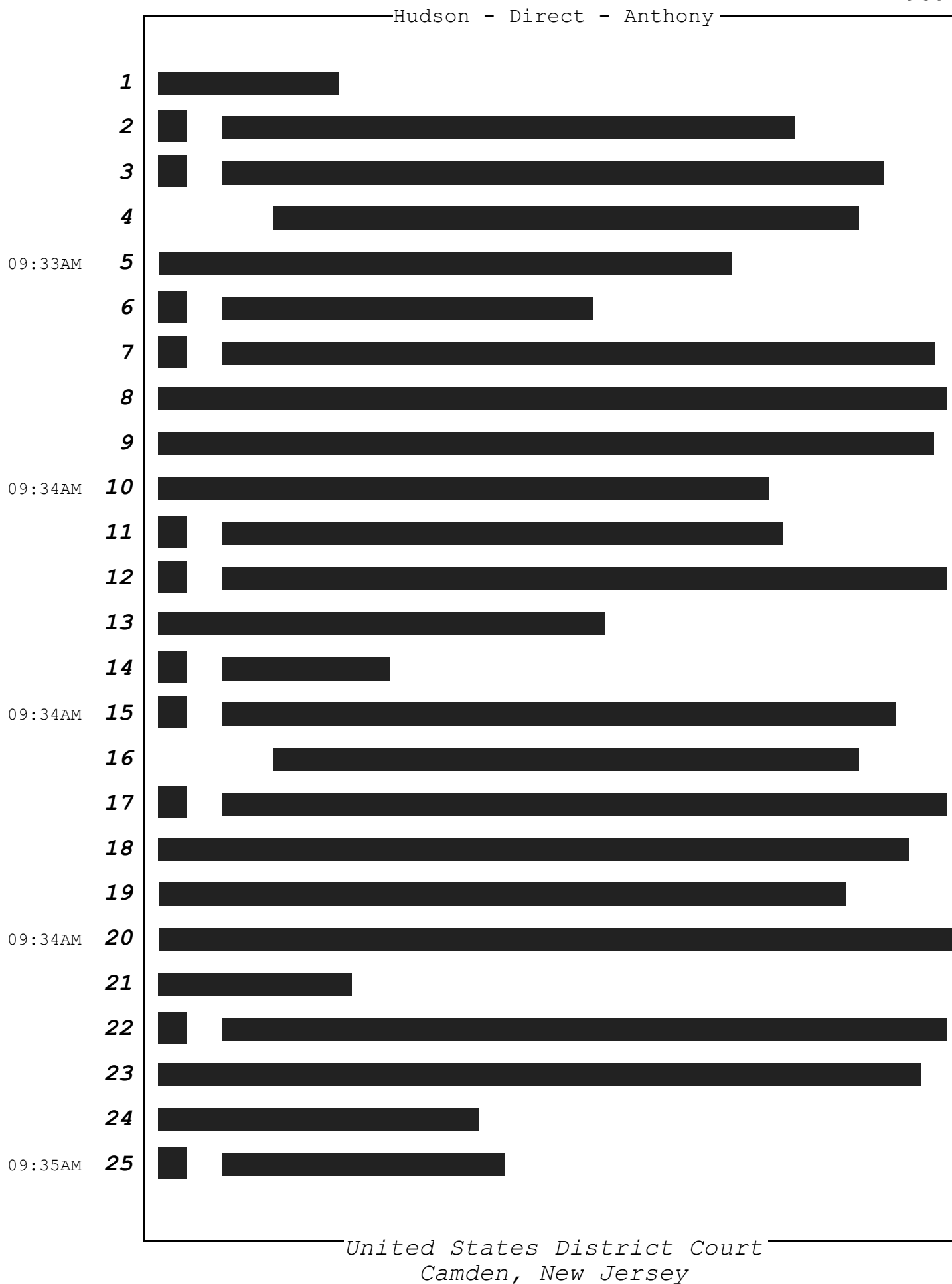


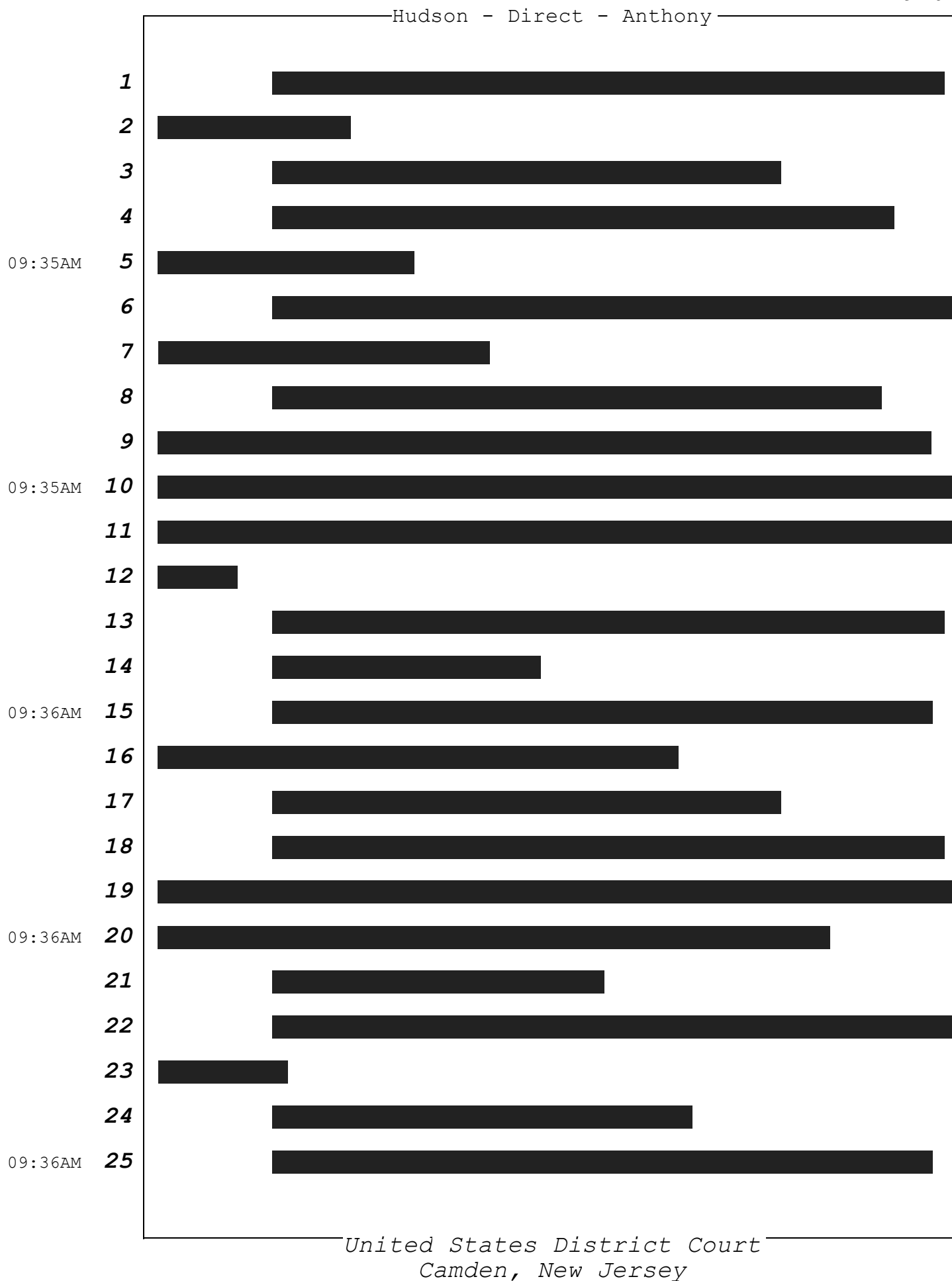


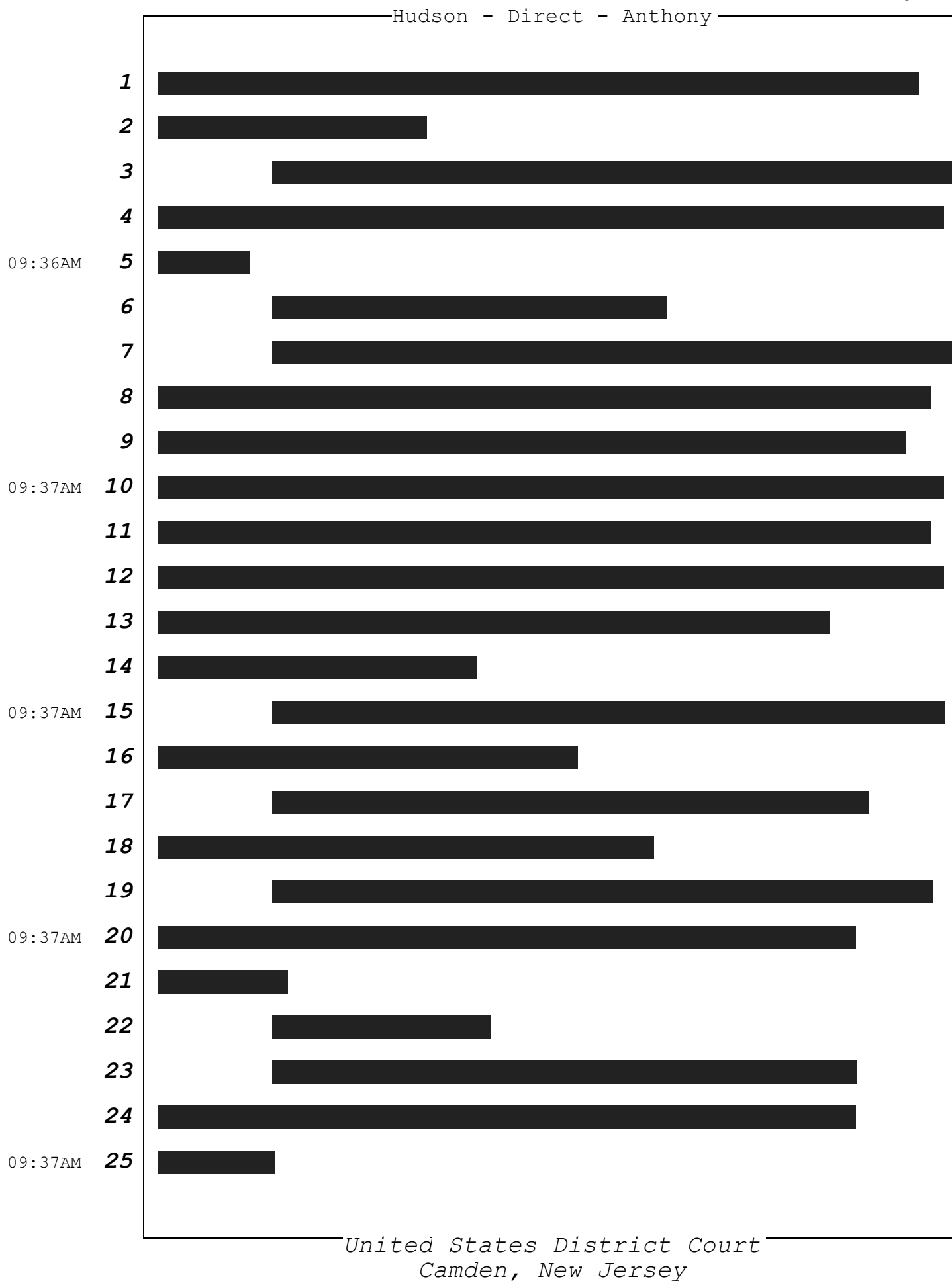


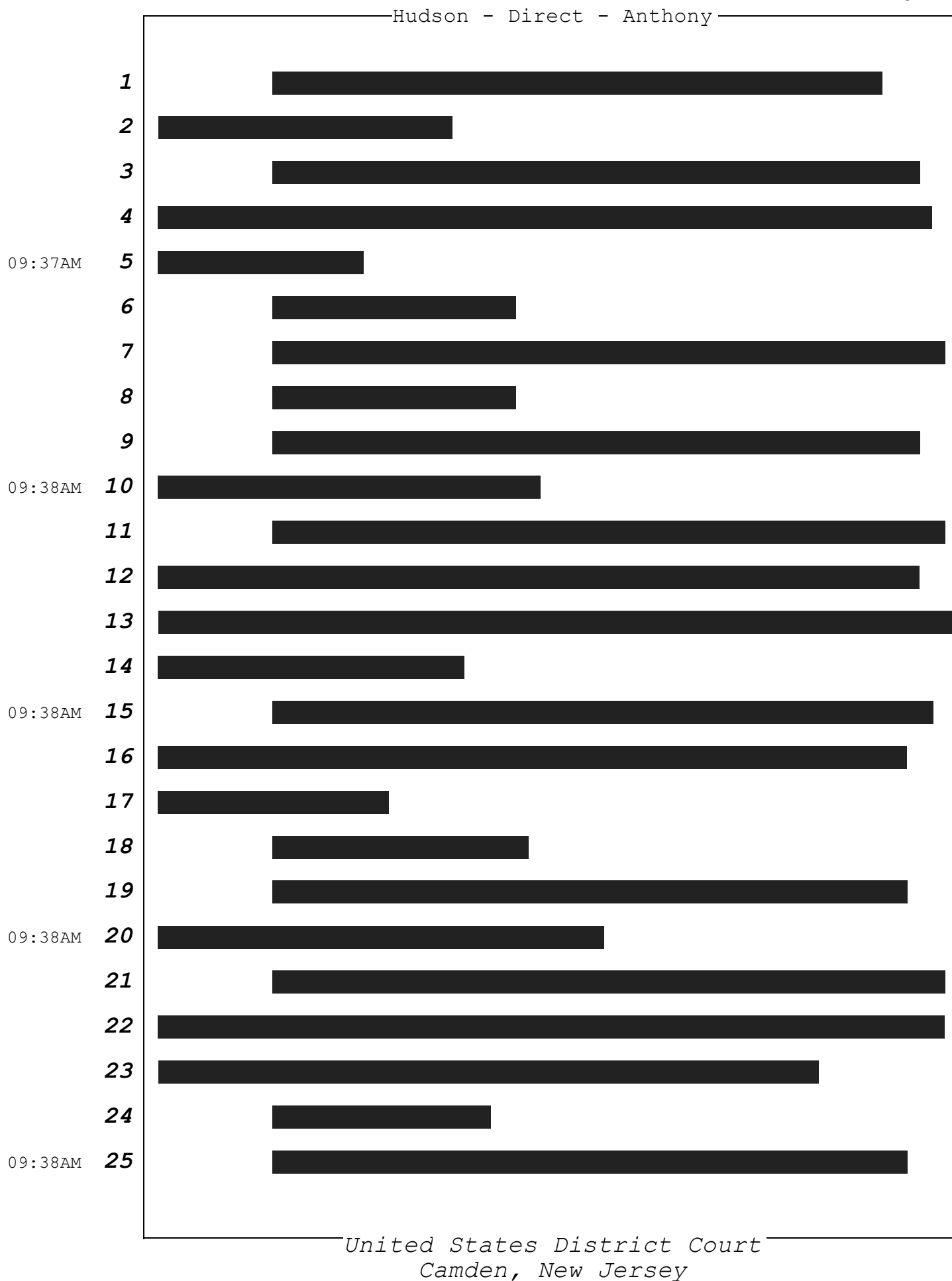


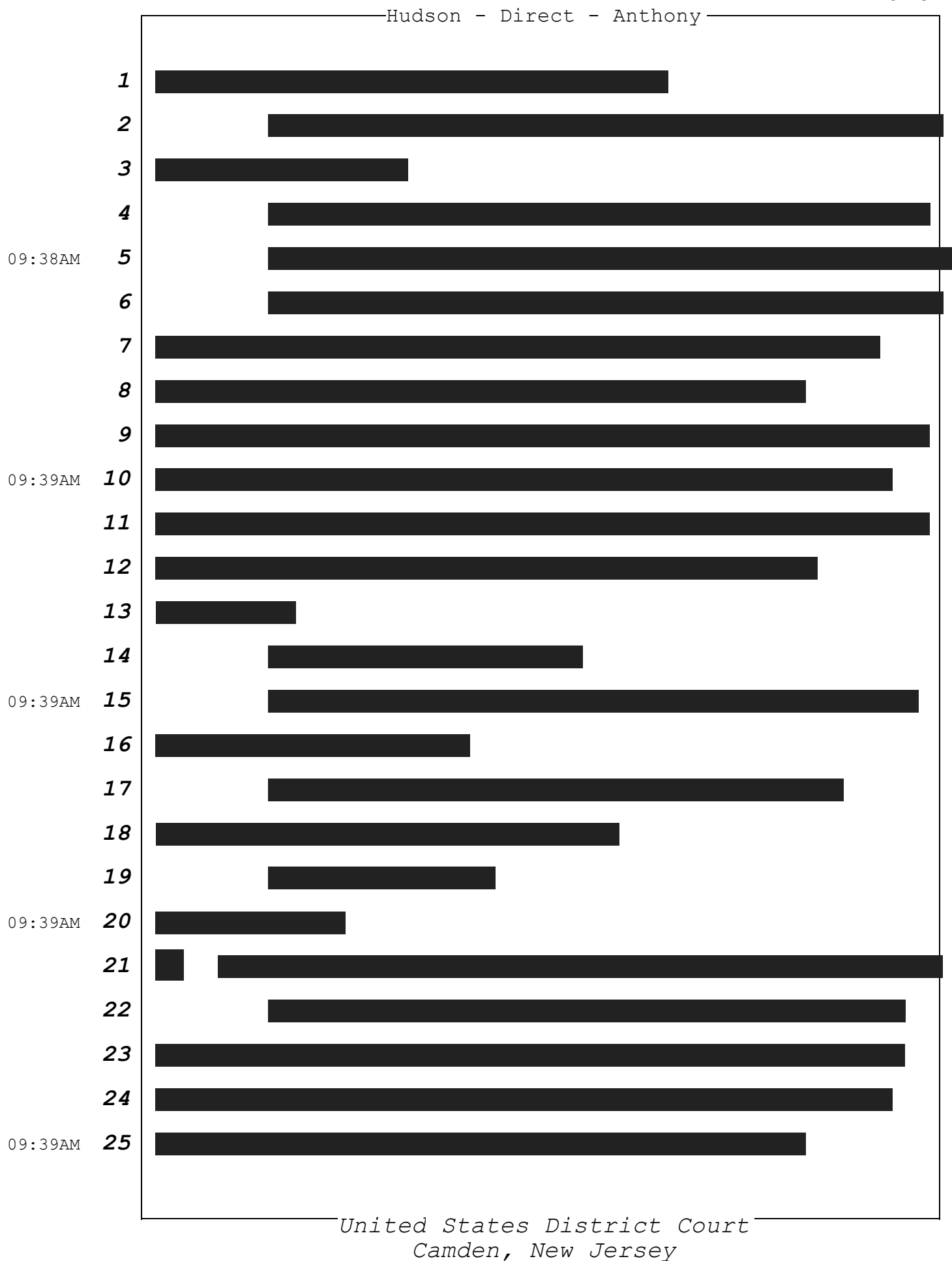




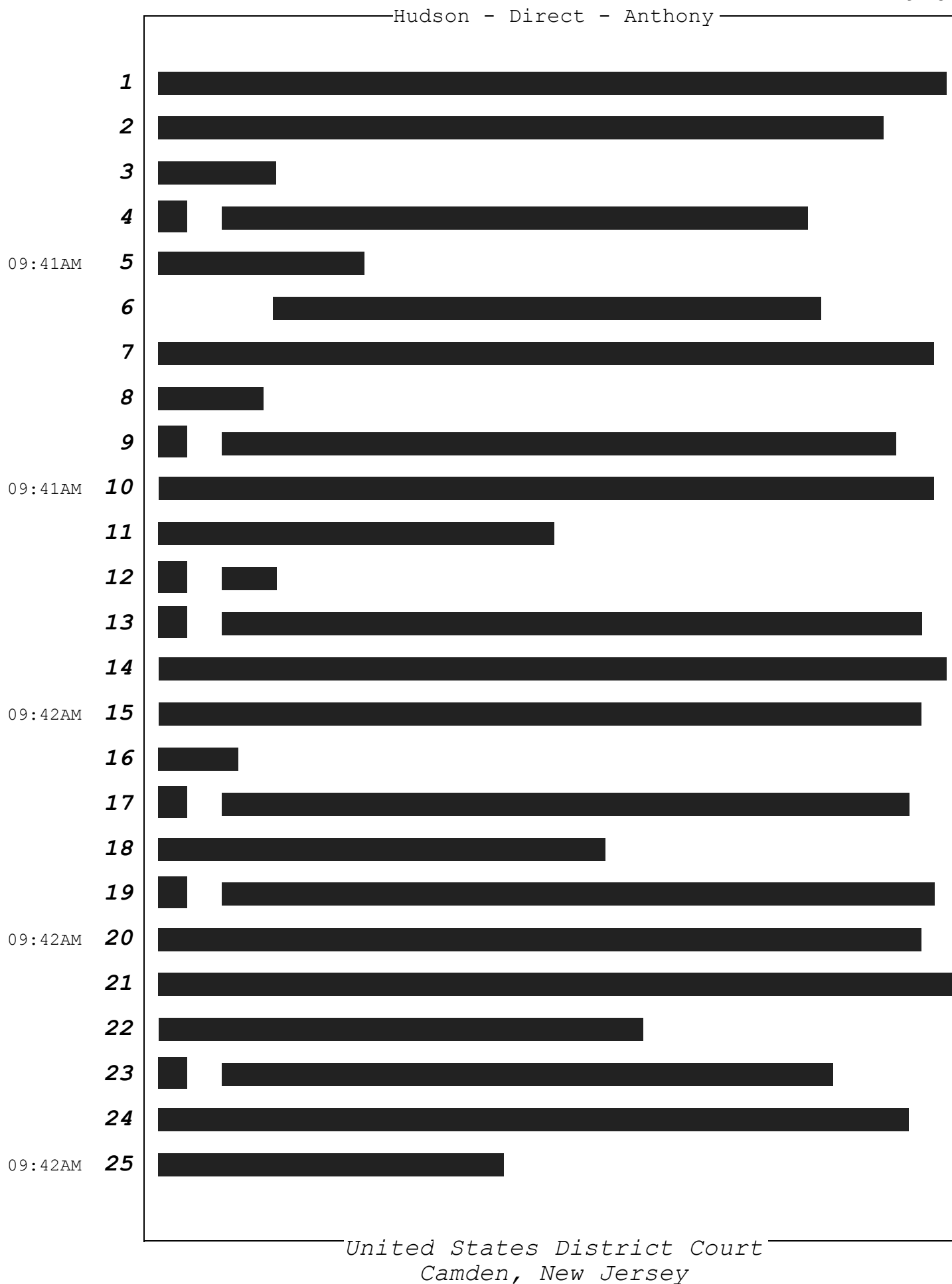


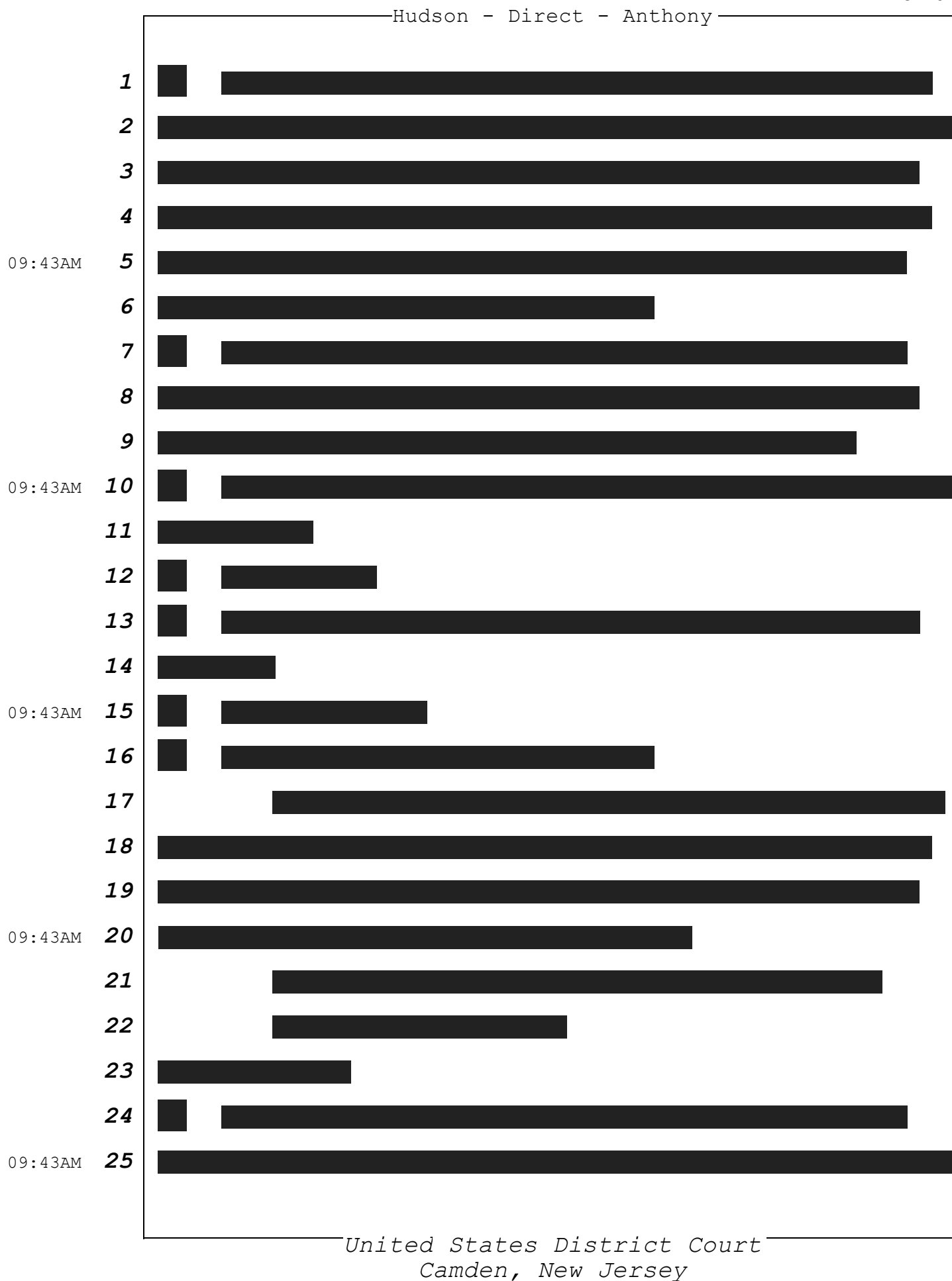










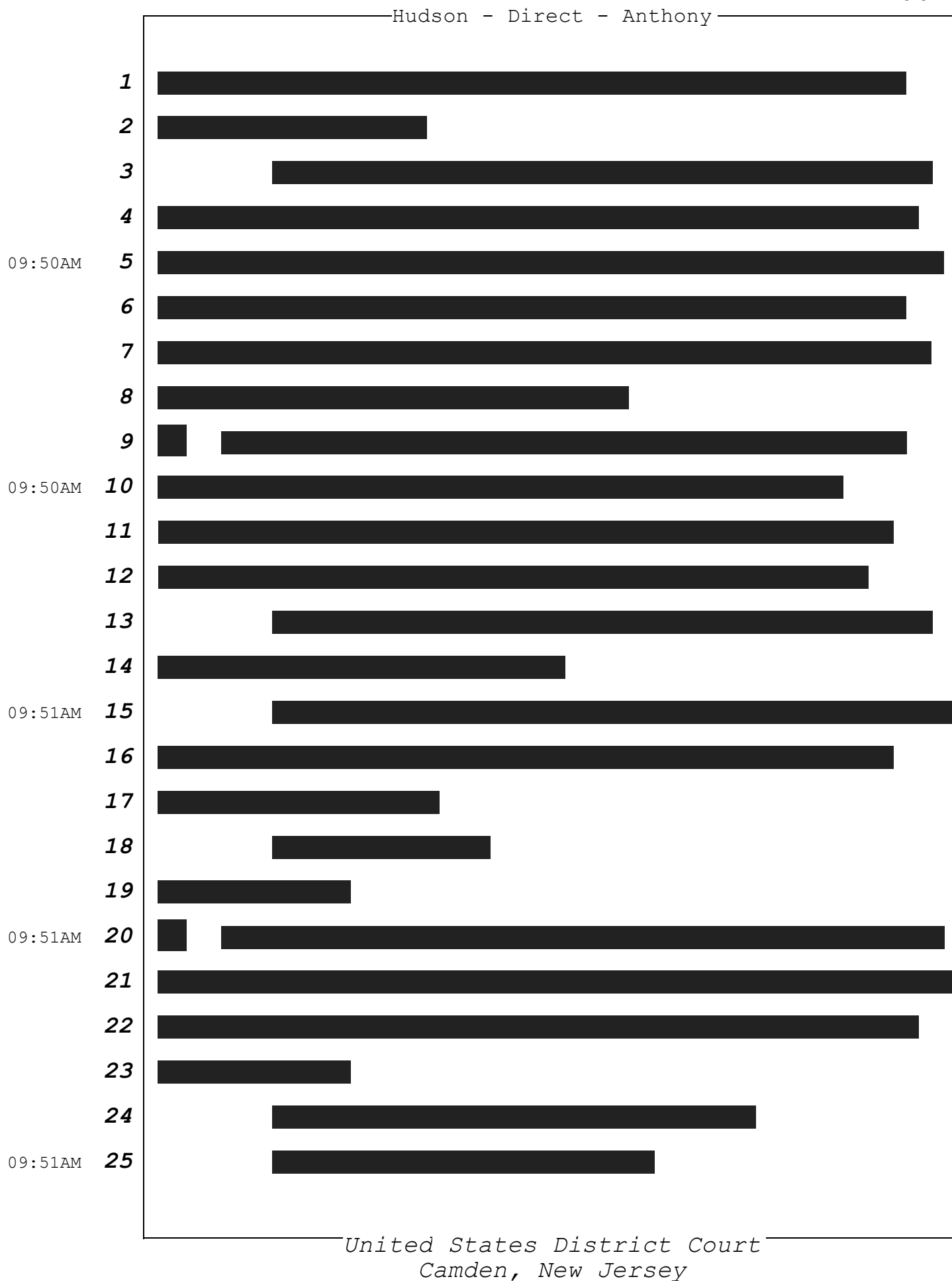


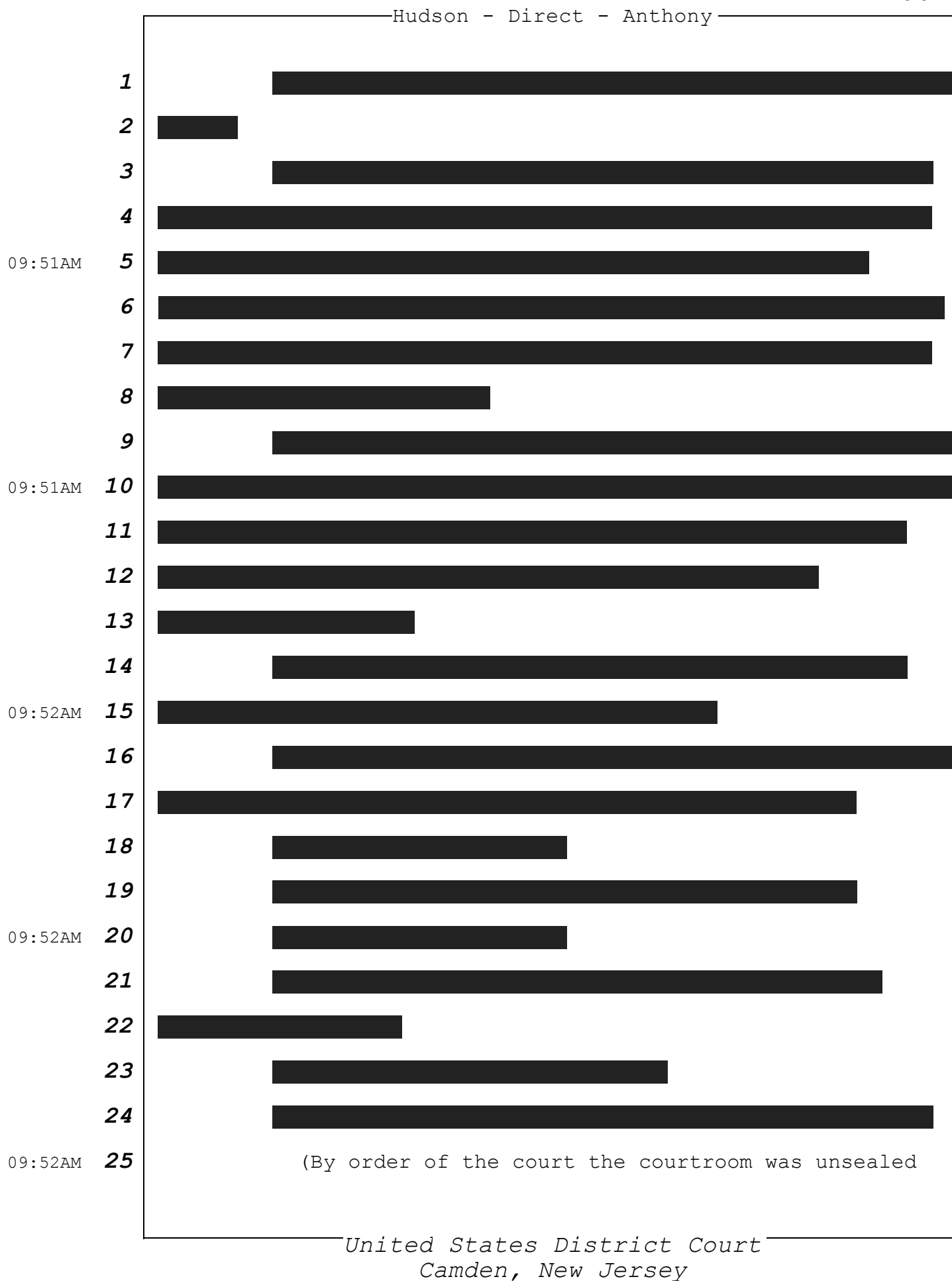












—Hudson - Direct - Anthony—

1 BY MR. ANTHONY:

2 Q. Mr. Hudson, now I'd like to turn to the effect of the
3 defendants' entry into the budesonide nebulized suspension
4 market on AstraZeneca's payroll.

09:52AM 5 Do you expect there would be an effect?

6 A. So medicines like Pulmicort Respules, at this stage in
7 their life cycle, become contribution positive. So what
8 happens is that for the first three or four years of launching
9 a medicine, you spend a lot of time investing in its growth
09:53AM 10 and its -- the data that is around it, the clinical study
11 programs. And then once you get past that, you start to --
12 your revenue starts to exceed what you spend on that. At that
13 stage you become contribution positive. At that point we use
14 that money to reinvest in R&D and other parts of the business.

09:53AM 15 For us, if we were to lose this, for example, it
16 would have a significant effect on manpower that we have in
17 our organization. An important thing to remember is not all
18 -- some, but not all attributed specifically to the task of
19 supporting respules. This is the financing of an organization
09:53AM 20 and this is when you use the revenues from medicines at this
21 stage to be able to do that, to grow brands in diabetes, like
22 I mentioned, brands in lung cancer.

23 So there would be a significant impact based on the
24 percentage of contribution from respules to the total profit
09:54AM 25 of the business in North America that would have a dramatic

—Hudson - Direct - Anthony—

1 impact on the number of employees that would have to leave our
2 organization.

3 Probably in the region of eight hundred people.

09:54AM 4 Q. I think you covered this in the answer you just gave, but
5 would those eight hundred people be people who work on
6 Pulmicort Respules?

7 A. It's more than that. There are a small number of people
8 supporting respules both in its delivery, its regulatory
9 support, its legal support and the distribution of its samples
09:54AM 10 and other promotion. But when you're running a business with
11 multiple medicines in growth phase that are contribution
12 negative, this is how you run a pharmaceutical company and
13 reinvest in innovation. So you end up taking the profit from
14 products that are in a profitable phase and you reinvest it in
09:54AM 15 people and R&D programs. And if you don't have that revenue,
16 you cut both.

17 Q. Now, has AstraZeneca announced other layoffs in recent
18 years totally unrelated to this?

19 A. We've been in a period of transformation for a number of
09:55AM 20 years. We've been a company that has been adjusting itself
21 down for maybe three, four, five years.

22 Q. If there were to come a time later on after a generic
23 launch by the three defendants in this case where their
24 products were taken off the market, would the effect of the
09:55AM 25 layoffs you described to the court be something that could be

—Hudson - Direct - Anthony—

1 easily reversed?

2 A. No. It doesn't work like that.

3 Q. Why not?

4 A. Well, because if you let people go, skilled people, these
09:55AM 5 are skilled people, don't forget. If you let people go, they
6 take both the sort of knowledge and capability with them, but
7 also they find alternative work. And that is the nature of
8 the beast. We would lose some high quality people and we
9 would try to recruit again, but it's a long process.

09:56AM 10 And, you know, running a pharmaceutical company, time
11 is of the essence. We don't talk a lot about time, but
12 finding time to recruit on that scale, if that was to be the
13 case, would be a huge budget and probably not achievable.

14 Q. Let me ask about research and development.

09:56AM 15 Would there be an effect on research and development
16 at AstraZeneca if the three defendants were permitted to
17 launch unlicensed generics?

18 MS. BRODY: Objection. Foundation, your Honor.

19 THE COURT: Yes. Lay the foundation.

09:56AM 20 MR. ANTHONY: Sure.

21 BY MR. ANTHONY:

22 Q. Could you explain to the court, does -- do any of your
23 job responsibilities relate to maintaining the infrastructure
24 of a research and development function at AstraZeneca?

09:56AM 25 A. So at the beginning when you asked me my

—Hudson - Direct - Anthony—

09:57AM 1 responsibilities, I made it clear, I think, that I'm on a
2 global executive team for AstraZeneca. I report to the CEO.
3 And tomorrow, again, I'll be in London working on the global
4 team and looking at our R&D pipeline and where investments can
5 be made.

6 Investments in medicines for lung cancer, ovarian
7 cancer, breast cancer and immunotherapies will be the
8 conversation.

09:57AM 9 The reality is you can't do that without profit from
10 medicines that are later in their life cycle. And so that is
11 the model for being an innovational pharmaceutical company.

12 If I did not feel the responsibility of returning
13 investment dollars to the R&D engine to try to figure out
14 break-through science, then I wouldn't be doing my job
09:57AM 15 properly.

16 Q. So now turning to my other question, what would the
17 effect be on research and development if the three defendants
18 were to launch unlicensed generic budesonide nebulized
19 suspension?

09:57AM 20 A. So you pick -- you could pick an annual report, say last
21 year's, and you could see the level of investment we make in
22 R&D. And somewhere between 16 and 18 percent, depending, of
23 our total revenues which is approximately four billion dollars
24 a year.

09:58AM 25 If you were to remove 400 million dollars,

—Hudson - Direct - Anthony—

1 approximately, of contribution, you're effectively doing two
2 things. You're wiping out 10 percent of the R&D spend, number
3 one. And number two, think about the actual programs that are
4 contained within that. These are individual phase three
09:58AM 5 programs. These are two, three hundred million dollar
6 programs per year, per year, that are at the phase just before
7 approval of bringing through medicines in oncology and
8 respiratory and diabetes.

9 Now, the complexity is -- and, of course, we invest
09:58AM 10 even at risk because we don't know what will come out at the
11 other end, but we have to make the investment decision and we
12 have to hope that the clinical trials show the positives. But
13 we would not be able to do that. It's an important point.
14 That would stop on a large part of our investment.

09:59AM 15 Q. Compared to the overall figure of \$4 billion, is the type
16 of reduction you're talking about not a very big deal?

17 A. I think it's well documented externally that we have an
18 incredibly promising pipe line at AstraZeneca, but it's just a
19 little bit out of reach. It's just a little bit further ahead
09:59AM 20 in front of us. We're extraordinarily tightly wound as an
21 organization, and what I mean by that is, you know, as
22 recently as the Q3 earnings call a week ago, the analysts are
23 trying to calculate do we have enough revenue to deliver on
24 the pipeline investments. Our science is great, but can we
10:00AM 25 get the science through the programs and into the market? And

—Hudson - Direct - Anthony—

1 that takes significant investment, and the analysts are always
2 trying to do the calculation to see whether you have enough
3 cash to be able to do that. So, they understand our
4 break-through science and what that means. They worry about
10:00AM 5 every dollar that we invest and where it comes from. And
6 that's the issue. That's why this is bigger than lost revenue
7 in principle. This is about what happens to that dollar and
8 what it could turn into for the organization.

9 Q. If AstraZeneca experienced a reduction in its ability to
10:00AM 10 fund -- let me start my question. I'll ask you a different
11 question.

12 Have you quantified how much of a reduction in research
13 and development funding would result from a generic launch by
14 the three defendants? You may have already answered this, but
10:01AM 15 I want to make sure I have it.

16 A. I quantified the lost revenue, and you have asked me what
17 you think -- what we would have in terms of sales and share.
18 So, we know that we lose over 90, 95 percent of that
19 opportunity. We've quantified what the sales are currently,
10:01AM 20 closer to \$500 million in total. And, you know, I've tried to
21 give context as to a \$4 billion dollar R&D investment. You
22 don't need to be a great mathematician to understand that is a
23 big number to lose from R&D.

24 Q. And if AstraZeneca lost that big number for R&D, how
10:01AM 25 would it be decided which projects to terminate or curtail?

—Hudson - Direct - Anthony—

1 A. Well, that's probably one of the most difficult
2 conversations I ever have as a leader in the pharmaceutical
3 industry. Sitting on the executive team for AstraZeneca where
4 we monthly go through what's called the late stage product
10:02AM 5 committee, we go through projects that we want to fund and we
6 go through the choices that we have to make, and we prioritize
7 break-through science, again, this is well documented, but we
8 also -- we have to make trade-offs and how do you choose
9 between lung cancer and ovarian cancer.

10:02AM 10 Some of that is timing. If you know that you have data
11 to be published and you know that you have income coming next
12 year, for example, in this case, let's say another three to
13 400 million dollars, you can phase programs to be able to
14 deliver the science and the clinical outcome. If you don't
10:02AM 15 have it, you have to choose between programs. And that's just
16 the harsh reality of trying to pick where you think you'll do
17 the best for patients with what you have in terms of dollars
18 to invest. I mean, it's complicated and it's, quite frankly,
19 very difficult, but it would have to be done.

10:02AM 20 Q. Continuing on this topic of lost revenue from an
21 unlicensed generic launch by the three defendants, if the
22 company anticipated there was a possibility of getting that
23 money back in damages at some later time in the litigation,
24 would that be a sufficient answer to the research and
10:03AM 25 development issue, to get a check later on?

—Hudson - Direct - Anthony—

1 A. Yeah, I've tried to be clear about this, which is that
2 lost revenue could probably be calculated. Lost investment on
3 that revenue in R&D is an almost impossible calculation to
4 make. How do you know which \$200 million investment in a
10:03AM 5 Phase III program will bear fruit? It could become a
6 multimillion dollar, multibillion dollar blockbuster, or it
7 could fail a Phase III study. You couldn't write a model to
8 calculate that. The dollars, the dollars in lost revenue,
9 whatever number you put on it, would be accurate only in terms
10:03AM 10 of sales. It would not even begin to compute what it would
11 take from the lost R&D investment.

12 Q. I want to go back to one topic you testified about
13 earlier with regard to the possibility of market shortages of
14 budesonide, budesonide nebulized suspension. Does AstraZeneca
10:04AM 15 currently have in place a practice of storehousing medicine to
16 guard against possible shortages?

17 A. Well, we do. We look at one of two ways. There are
18 medicines in launch phase where we don't know quite what the
19 demand will be because these are medicines that physicians,
10:04AM 20 clinicians are just starting to understand and find a place
21 for. So, we manufacture slightly ahead of a forecast to make
22 sure that we can always satisfy demand if physicians want
23 them. Later, for example, in this situation, we try and
24 manufacture, where possible, a small amount of what we call
10:05AM 25 buffer stock, so several weeks beyond what is normally in the

—Hudson - Direct - Anthony—

1 chain to allow for a short-term outage, a short-term out of
2 stock, for example, but that is really for a -- that's really
3 thinking, if, for example, Teva were unable to supply because
4 of a late shipment, a late validation or a batch failure, but
10:05AM 5 it's not -- it can't compensate for a complete failure to
6 supply the market, which is back to your Toprol example of
7 earlier. That's the piece where I tried to make it clear that
8 if you are a 5 million unit a year company and suddenly you're
9 asked to produce 150 million units a year, it's a long project
10:05AM 10 to come back from that. So, you can't carry that amount of
11 stock just in case. It's just not possible.
12 Q. Let me ask you about in the case of Pulmicort Respules®,
13 the amount of stock that AstraZeneca carries as a buffer under
14 current market conditions. Would that change, would a
10:06AM 15 company's willingness to carry that kind of a buffer change if
16 the three defendants were to launch unlicensed generic
17 products?
18 A. Well, we'd -- we'd have to make an assumption that we'd
19 review it. I forget what it is now, about six weeks or
10:06AM 20 something like that. It's modest based on what we went
21 through before. Once the value is gone from the market and
22 the manufacturing capacity is now a discussion point because
23 we're not -- it's not a profitable place for us to be and
24 there are alternatives, I would say that we would reduce that.
10:06AM 25 There is a value attributed to stock in the pipeline that is

—Hudson - Direct - Anthony—

1 material. So, we would probably reduce that significantly.

2 Q. I'd like to ask you about formulary status and the
3 formulary status of Pulmicort Respules®. Could you explain to
4 the Court what a formulary is?

10:07AM 5 A. Well, typically it is described as tier 1, tier 2, tier
6 3, tier 4, and specialty, which is where managed care
7 organizations or say a CIGNA or an Aetna or one of these
8 organizations will say products in tier 1 is fully covered by
9 their plan as a generic medicine, for example. Tier 2 might
10:07AM 10 be a preferred branded medicine. Tier 3 might be a medicine
11 that is for very specific patient populations only and there
12 are some prior authorizations. I think it's known as well a
13 physician would have to make a phone call to the plan to get
14 the medicine given. And tier 4 is really very specialized,
10:07AM 15 actually, and difficult.

16 Q. Based on your experience, do you have an understanding of
17 what would happen to Pulmicort Respules®'s formulary status if
18 the three defendants were to launch unlicensed generics?

19 A. Well, I mentioned earlier about the radical reduction in
10:08AM 20 price. So, consequently, if we -- we would have to reduce our
21 price to maintain any type of access on the tier, but it's
22 most likely we would disappear off the list of medicines at
23 any tier with low cost generics being in tier 1. And we
24 probably, actually, it's possible we would retain some of our
10:08AM 25 Medicaid business, which is the unprofitable part of our

—Hudson - Direct - Anthony—

1 business, just because of the way Medicaid is calculated
2 across our entire portfolio, not just across Pulmicort
3 Respules® themselves.

10:08AM 4 MR. ANTHONY: Your Honor, may I have a moment to
5 confer with counsel?

6 THE COURT: Yes.

7 MR. ANTHONY: I do have a couple more questions, if I
8 may, your Honor.

9 THE COURT: Okay.

10:09AM 10 BY MR. ANTHONY:

11 Q. Mr. Hudson, you testified earlier about the Teva
12 agreement. I'm not going to ask you about percentages now.
13 In this open courtroom I have a different question for you.
14 Is that agreement still in force?

10:09AM 15 A. Yes.

16 Q. Is Teva still paying?

17 A. Yes, absolutely.

18 Q. And if you can answer this without giving specific
19 percentages, I would appreciate it, but does the existence of
10:09AM 20 that agreement and that royalty structure have an effect on
21 AstraZeneca's ability to react to the launch of three
22 unauthorized generics in this case in terms of price erosion?

23 THE COURT: In terms of what?

24 MR. ANTHONY: Price erosion.

10:10AM 25 (By order of the court the courtroom was sealed.)

Hudson - Direct - Anthony

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
10:10AM 5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10:10AM 10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
10:11AM 15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 (By order of the Court, the testimony was unsealed.)
10:11AM 20 MR. ANTHONY: Thank you, Mr. Hudson. I appreciate
21 it.
22 Your Honor, there was one --
23 THE COURT: So, that last answer should be sealed.
24 MR. ANTHONY: Very well.
10:11AM 25 THE COURT: Yes.

United States District Court
Camden, New Jersey

HUDSON - CROSS - BRODY

1 MR. ANTHONY: Thank you. I pass the witness. Thank
2 you.

3 THE COURT: So, the record will reflect the last
4 answer from the witness will be sealed.

10:11AM 5 MS. BRODY: Good morning, your Honor. Good morning,
6 Mr. Hudson.

7 THE COURT: Yes.

8 THE WITNESS: Good morning.

9 MS. BRODY: Your Honor, may we approach with binders?

10:12AM 10 THE COURT: Yes.

11 (CROSS EXAMINATION OF MR. HUDSON BY MS. BRODY:)

12 Q. Mr. Hudson, do you have your two binders now that were
13 handed up?

14 A. I do, yes.

10:13AM 15 Q. Mr. Hudson, will you understand if I refer to B-I-S or
16 BIS today, that means budesonide inhalation suspension?

17 A. Yes.

18 Q. And if I refer to Watson today, will you understand that
19 I refer to Breath and Watson collectively?

10:13AM 20 A. Yes.

21 Q. And you understand Watson is a defendant to this
22 litigation, correct?

23 A. Correct.

24 Q. Now, you understand that certain AstraZeneca employees
10:13AM 25 have submitted written submissions in the form of declarations

—HUDSON - CROSS - BRODY—

1 in this litigation to support AstraZeneca's request for
2 injunctive relief, correct?

3 A. Correct.

4 Q. And those declarations have described alleged harms

10:13AM **5** AstraZeneca would incur if defendants launched their generic
6 BIS products, correct?

7 A. Correct.

8 Q. And one of those declarations were submitted on behalf of
9 a Linda Palczuk, correct?

10:13AM **10** A. Correct.

11 Q. And that's P-A-L-C-Z-U-K.

12 A. Palczuk.

13 Q. Another was Marion McCourt, correct?

14 A. Correct.

10:14AM **15** Q. Ms. Palczuk is still employed at AstraZeneca to your
16 knowledge, correct?

17 A. Correct.

18 Q. Do you know if Ms. Palczuk intends to testify during
19 these trial proceedings?

10:14AM **20** A. I don't know.

21 Q. Do you know if Ms. McCourt intends to testify during
22 these trial proceedings?

23 A. I don't know.

24 Q. You have not spoken with Ms. Palczuk concerning any harm
10:14AM **25** issues relevant to this litigation, correct?

HUDSON - CROSS - BRODY

1 A. Correct.

2 Q. And you have not spoken with Ms. McCourt concerning any
3 harm issues relevant to this litigation, correct?

4 A. Correct.

10:14AM 5 Q. And you have never submitted any written submission,
6 including any declaration, in this litigation to support
7 AstraZeneca's request for injunctive relief, correct?

8 A. Correct.

9 Q. And you did not speak with AstraZeneca's expert, Dr.
10:14AM 10 Vellturo, concerning harm issues relevant to this litigation,
11 correct?

12 A. Correct.

13 Q. Are you relying upon any statements made in the Palczuk
14 or McCourt declarations submitted in this litigation to
10:15AM 15 support your harm opinions?

16 A. Firstly, I'm relying on a career of expertise in the
17 industry, and I have read their declarations and I have
18 reflected on their comments and I have my own view which I'm
19 answering questions on today.

10:15AM 20 Q. Are you relying upon any statements made in the Palczuk
21 or McCourt declarations submitted in this litigation to
22 support your harm opinions today?

23 MR. ANTHONY: Objection.

24 THE COURT: No, I'll allow it.

10:15AM 25 THE WITNESS: Not specifically.

—HUDSON - CROSS - BRODY—

1 BY MS. BRODY:

2 Q. Generally?

3 A. Well, if my view was the same as what I read, it's hard
4 for me to say am I relying on it or was it my view.

10:15AM 5 Q. Now, I want to get the timeline straight here, Mr.

6 Hudson. You only first joined an AstraZeneca entity in 2006,
7 correct?

8 A. Correct.

9 Q. And that entity was AstraZeneca U.K. located in the

10:16AM 10 United Kingdom, correct?

11 A. Correct.

12 Q. You were at AstraZeneca U.K. until 2008, correct?

13 A. Correct.

14 Q. That was April 2008?

10:16AM 15 A. Correct.

16 Q. And while you were employed at AstraZeneca U.K., you did
17 not have responsibility for AstraZeneca's Pulmicort Respules®
18 products sold in the United States, correct?

19 A. Correct.

10:16AM 20 Q. From your position at AstraZeneca U.K., you went on to
21 work at AstraZeneca Spain, correct?

22 A. Correct.

23 Q. You were there until 2011, correct?

24 A. Correct.

10:16AM 25 Q. And while you were employed at AstraZeneca Spain from

—HUDSON - CROSS - BRODY—

1 2008 to 2011, you did not have any responsibility for
2 AstraZeneca's Pulmicort Respules® products sold in the United
3 States, correct?

4 A. Correct.

10:16AM 5 Q. Then you were at AstraZeneca KK in Japan from April 2011
6 to January 2013, correct?

7 A. Correct.

8 Q. And while you were employed at AstraZeneca in Japan from
9 April 2011 to January 2013, you did not have responsibility
10:17AM 10 for AstraZeneca's Pulmicort Respules® products sold in the
11 United States, correct?

12 A. Correct.

13 Q. Your role at AstraZeneca with respect to the sale of
14 products in North America and the United States began only in
10:17AM 15 January '13, 2013, excuse me, or about two years ago, correct?

16 A. Correct.

17 Q. So, any responsibility you may have had or you have for
18 Pulmicort Respules® in the U.S. market only began in January
19 2013, correct?

10:17AM 20 A. Correct.

21 Q. Now, you do not know how much money AstraZeneca invested
22 in manufacturing and seeking approval for Pulmicort Respules®
23 in the United States, do you?

24 A. No.

10:17AM 25 Q. And you were not involved in AstraZeneca's decision to

—HUDSON - CROSS - BRODY—

1 file a new drug application for Pulmicort Respules®, correct?

2 A. Correct.

3 Q. And you did not have any involvement in AstraZeneca's

4 decision to manufacture Pulmicort Respules® for the U.S.

10:18AM 5 market in the early 2000s, correct?

6 A. Correct.

7 Q. Now, prior to 2013, you did not have any specific

8 knowledge concerning reinvestment of profits in research and

9 development as it relates specifically to Pulmicort Respules®,

10:18AM 10 correct?

11 A. I would say that's too specific a point. The reality is,

12 running businesses in Spain and Japan, clearly I understood

13 the importance of reinvesting profits from the entire global

14 revenues in R&D. The specific contribution made by Respules®,

10:18AM 15 no.

16 Q. Now, AstraZeneca is a top 10 global pharmaceutical

17 company, correct?

18 A. Correct.

19 Q. And you understand that AstraZeneca's scenario plans with

10:19AM 20 respect to anticipated product sales, correct?

21 A. Correct.

22 Q. And those scenario plans include forecasts of anticipated

23 future sales of products, whether in terms of dollars or

24 units, correct?

10:19AM 25 A. Correct.

HUDSON - CROSS - BRODY

1 Q. And AstraZeneca has prepared scenario plans or forecasts
2 relevant to anticipated sales of Pulmicort Respules®, correct?

3 A. Correct.

4 Q. And AstraZeneca prepares such forecasts or scenario plans
5 in the ordinary course of business, correct?

6 A. Correct.

7 Q. As part of your current job responsibilities at
8 AstraZeneca, Mr. Hudson, you have had a role in projecting
9 sales and preparing forecasts relevant to Pulmicort Respules®

10 in the United States, correct?

11 A. By preparing forecasts, could you be more specific,
12 please?

13 Q. Have you had a role in reviewing the output of software
14 or computations of forecasts that AstraZeneca has prepared
15 relevant to Pulmicort Respules®?

16 A. Correct.

17 Q. And the last forecasts you reviewed for Pulmicort
18 Respules® was as recent as September 2014, correct?

19 A. Correct.

20 Q. And that forecast was prepared in or around September
21 2014, correct?

22 A. Correct.

23 Q. Now, that latest forecast you reviewed in September 2014,
24 it showed a decline in price and volume for the 2014 and 2015
25 years ending through 2019 for Pulmicort Respules®, correct?

HUDSON - CROSS - BRODY

1 A. Correct.

2 Q. And that forecast for Pulmicort Respules® you reviewed in
3 September 2014, it showed anticipated future sales in terms of
4 both dollars and units, correct?

10:20AM 5 A. Correct.

6 Q. And in that forecast, the dollar value for 2014 for
7 Pulmicort Respules® was in the region of \$400 million,
8 correct?

9 A. Correct.

10:21AM 10 Q. And that \$400 million amount included royalties
11 AstraZeneca anticipates receiving from Teva for the sale of
12 its generic BIS products, correct?

13 A. Correct.

14 Q. Based on the latest forecasts you recall reviewing in
10:21AM 15 September 2014, the forecasted dollar sales for Pulmicort
16 Respules® in 2014 without royalties paid by Teva were
17 approximately \$120 or \$130 million, correct?

18 A. Approximately, yes.

19 Q. And for the 2015 year, those dollar values decline,
10:21AM 20 correct?

21 A. By a low single digit, yes.

22 Q. But the numbers do show some decline, correct?

23 A. Correct.

24 Q. And that decline occurs even without generic entry,
10:21AM 25 correct?

HUDSON - CROSS - BRODY

1 A. Correct.

2 Q. You agree that as a general matter, AstraZeneca forecasts
3 the impact of potential generic entry?

4 A. Yes, correct.

10:21AM 5 Q. Now, the forecast you testified that was prepared in
6 September 2014 by AstraZeneca and that you reviewed, you did
7 not look at that forecast in your direct testimony today, did
8 you?

9 A. Sorry. Could you ask the question again, please?

10:22AM 10 Q. You testified that you reviewed a forecast for Pulmicort
11 Respules® that was prepared by AstraZeneca in September 2014,
12 correct?

13 A. Correct.

14 Q. Did you see that forecast during your direct examination
10:22AM 15 today?

16 A. No.

17 THE COURT: Were you asked about it today?

18 THE WITNESS: No.

19 BY MS. BRODY:

10:22AM 20 Q. Do you know if that forecast was provided to defendants
21 in this litigation?

22 A. I don't know the answer to that.

23 Q. Now, AstraZeneca prepares forecasts to take into account
24 a potential at-risk launch, correct?

10:22AM 25 A. Correct.

—HUDSON - CROSS - BRODY—

1 Q. And when AstraZeneca considers at-risk launches in its
2 forecasting scenarios, it takes into account standard
3 assumptions with respect to, for example, pricing, correct?

4 A. Correct.

10:23AM 5 Q. Within your current job responsibilities at AstraZeneca,
6 Mr. Hudson, you have seen forecasts for Pulmicort Respules®
7 that take into account potential at-risk launch scenarios by
8 generics, correct?

9 A. Correct.

10:23AM 10 Q. And you saw such financial scenarios as recent as mid
11 year 2014, correct?

12 A. Correct.

13 Q. The last forecast you reviewed in September 2014 also
14 included as a possible scenario an at-risk launch by a
10:23AM 15 generic, correct?

16 A. Yes, correct.

17 Q. So, based on the forecast information you have seen,
18 including as recent as September 2014, AstraZeneca has at
19 least estimated what impact an at-risk launch by defendants to
10:23AM 20 this litigation would have on its sales, correct?

21 A. Correct.

22 Q. And that impact is measured in terms of both dollar and
23 unit sales, correct?

24 A. Correct.

10:24AM 25 Q. But again, you did not look at any forecasts that

HUDSON - CROSS - BRODY

1 included an at-risk launch scenario during your direct
2 testimony today, did you?

3 A. I commented on what I thought the most likely drop in
4 revenue would be.

10:24AM 5 Q. Did you see any or were you asked specifically about any
6 forecasts that included an at-risk launch scenario for
7 Pulmicort Respules® during your direct examination today?

8 A. I can't remember specifically how the question was asked,
9 but I remember arriving at an answer that showed the new low
10:24AM 10 sales number which would have been as part of the output of
11 the launch of generics, yes.

12 Q. And during your direct examination, did you physically
13 see an at-risk launch forecast that would have supported your
14 testimony?

10:24AM 15 A. No.

16 Q. Now, Mr. Hudson, Teva already has a generic BIS product
17 on the market, correct?

18 A. Correct.

19 Q. And that Teva BIS product has been on the market under a
10:25AM 20 license from AstraZeneca since 2009, correct?

21 A. Correct.

22 Q. You had no responsibility for Pulmicort® in the United
23 States when Teva launched its generic BIS product, correct?

24 A. Correct.

10:25AM 25 MS. BRODY: And, your Honor, I am going to start

HUDSON - CROSS - BRODY

1 talking about the license agreement and royalty amounts. So,
2 I think that it would be appropriate to seal the courtroom.

3 THE COURT: Okay. Why don't we take our morning
4 break. We'll take a 10-minute break and then, when we come
10:25AM 5 back, the courtroom will be sealed. Okay?

6 THE DEPUTY COURT CLERK: All rise.

7 (Recess at 10:25 a.m..)

8 (In open court at 11:03 a.m..)

9 THE DEPUTY COURT CLERK: All rise.

11:03AM 10 THE COURT: I apologize. A matter had come up.
11 Okay. Be seated.

12 Mr. Hudson. Ms. Brody.

13 MS. BRODY: And, your Honor --

14 THE COURT: Yes, the courtroom is sealed now. So,
11:03AM 15 the courtroom will be sealed. Thank you.

16 (By order of the Court, the courtroom was sealed.)

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

11:04AM 20 [REDACTED]

21 [REDACTED]

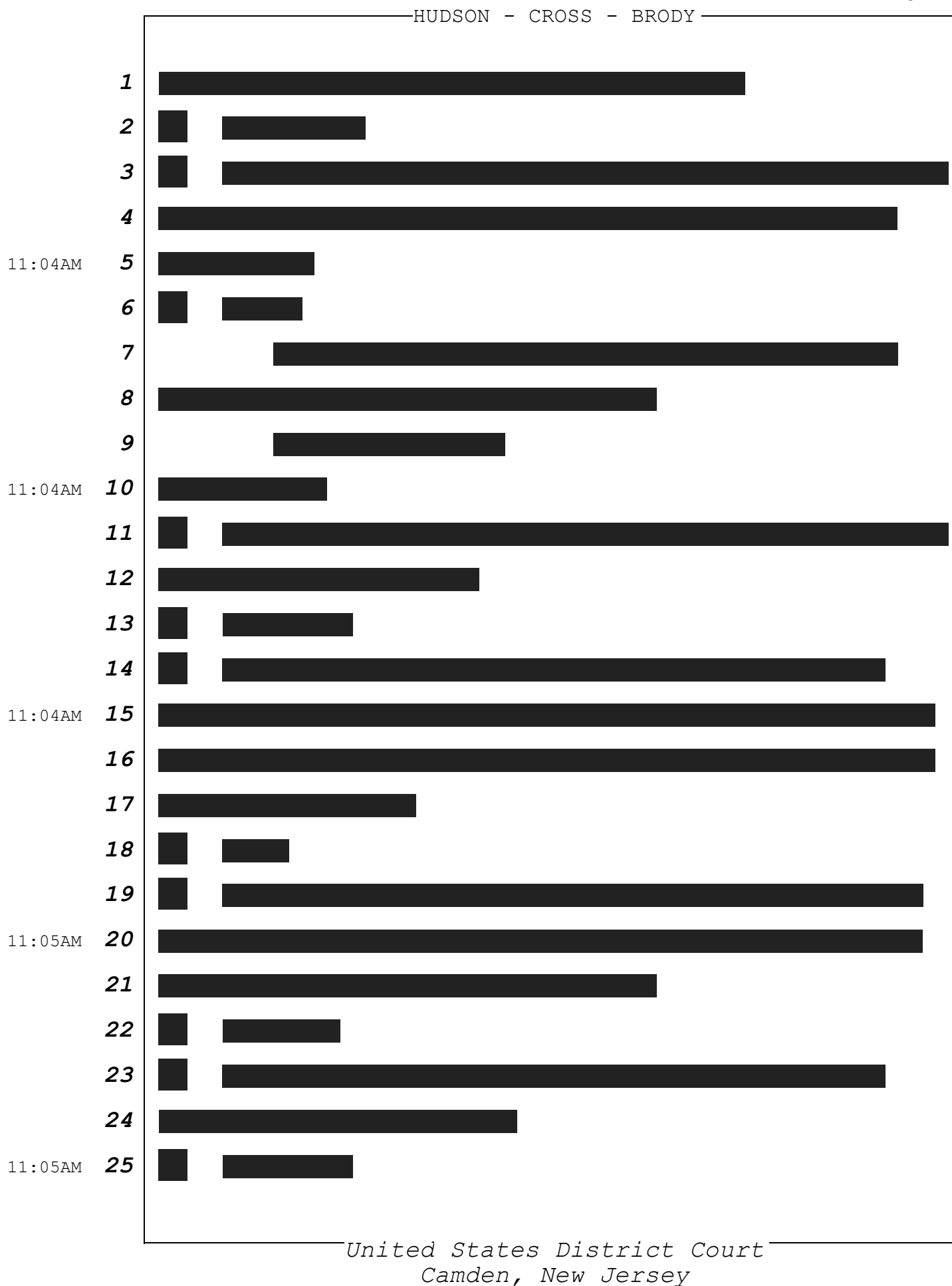
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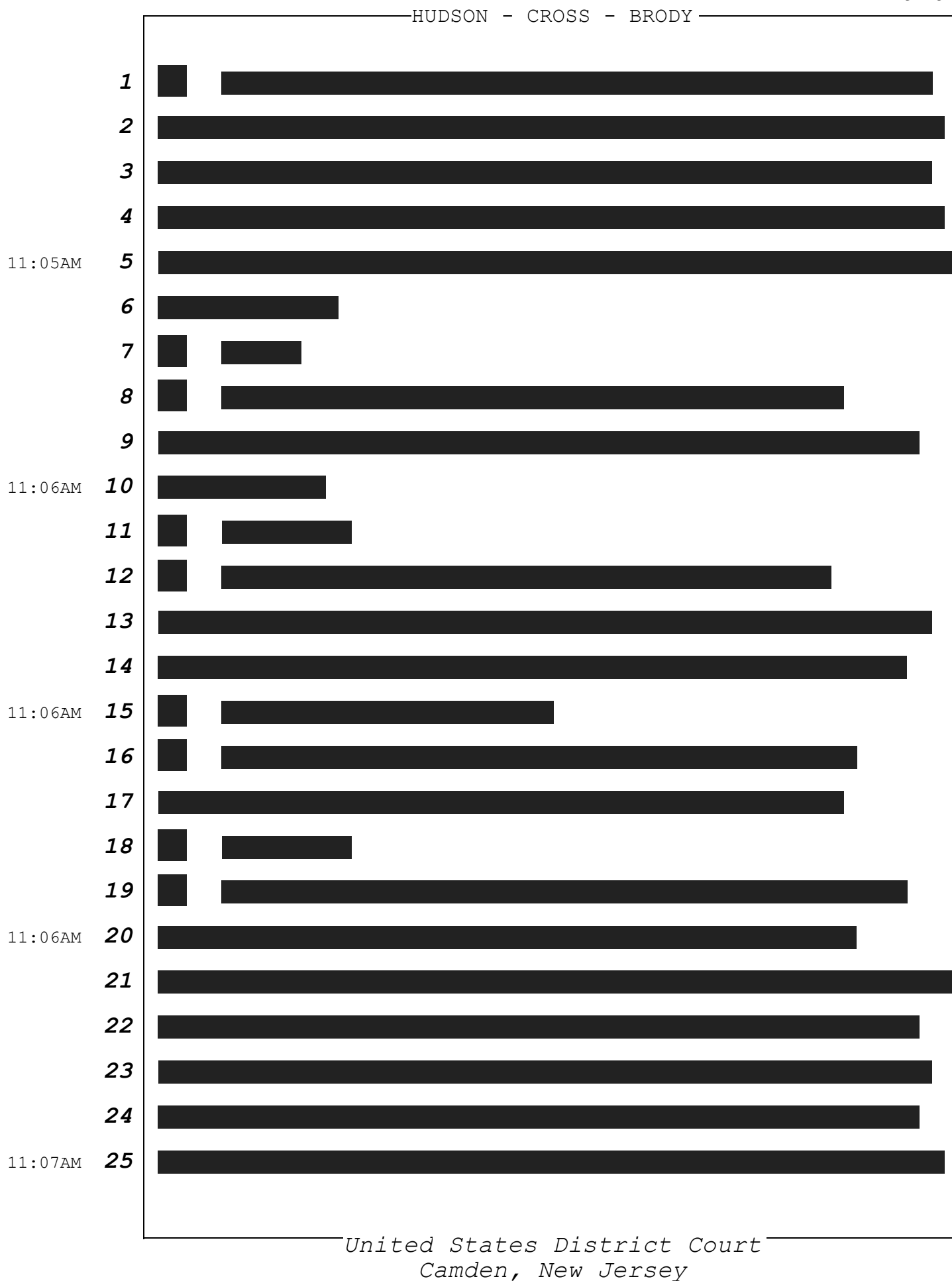
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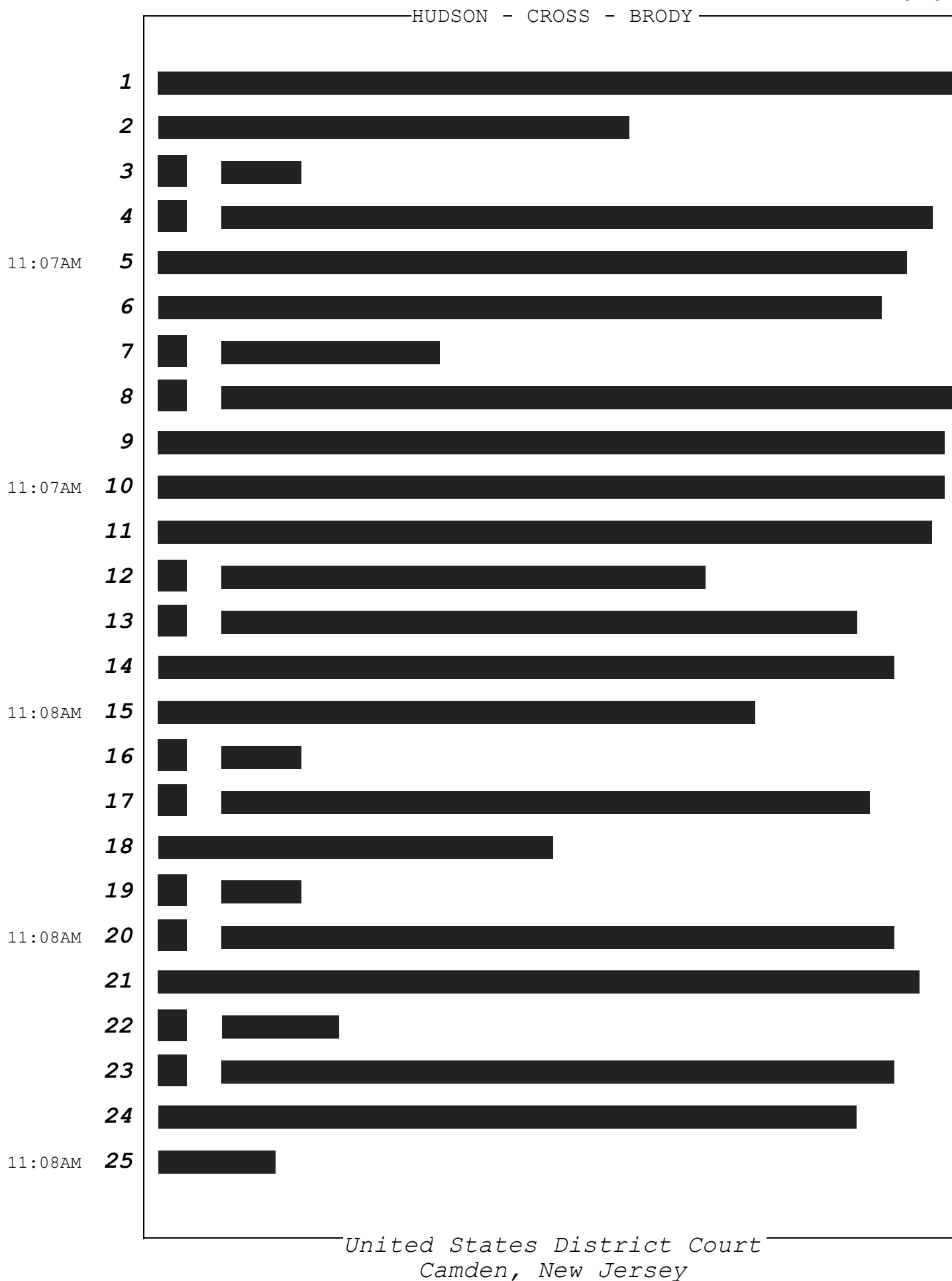
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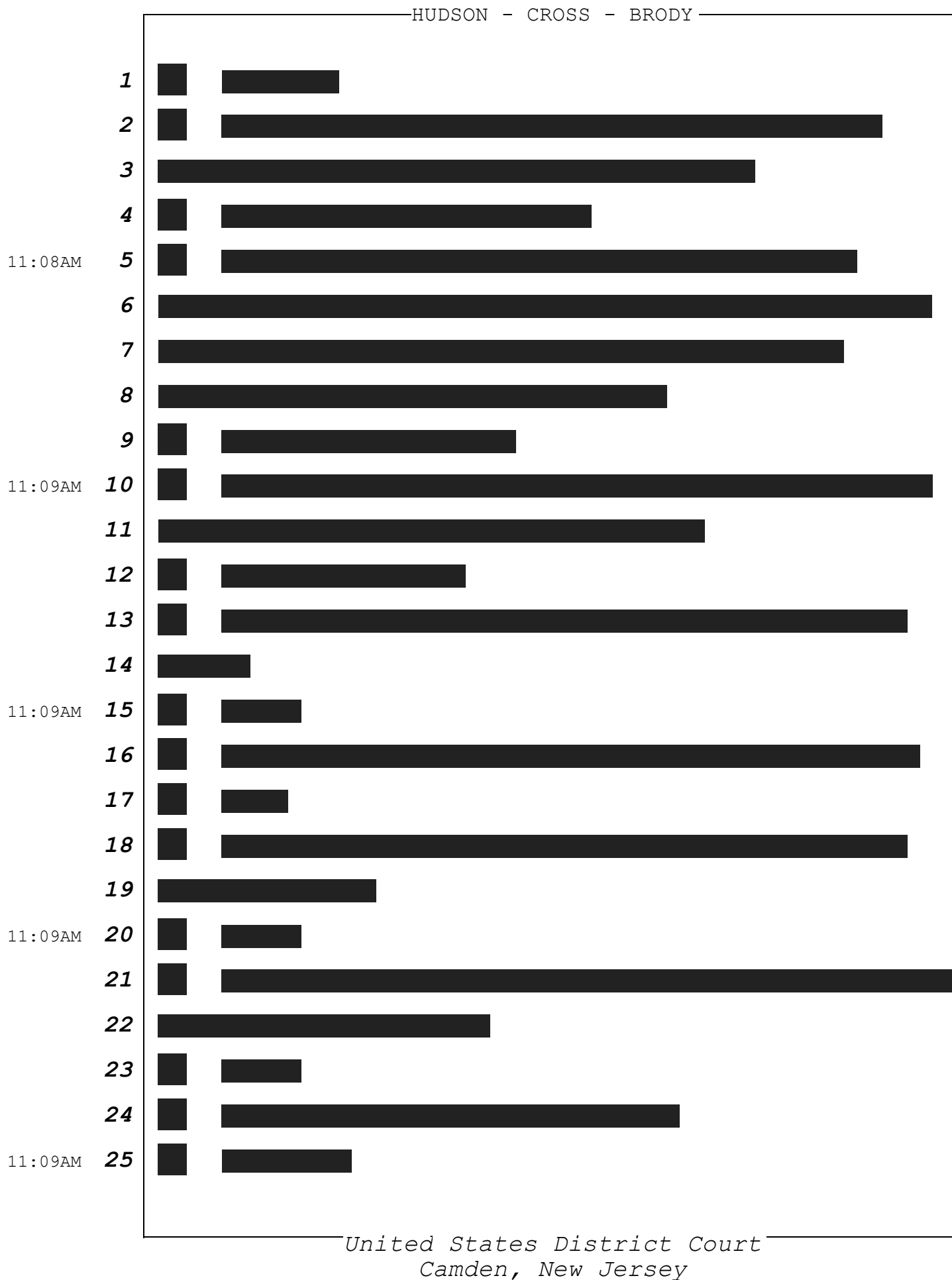
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United States District Court
Camden, New Jersey



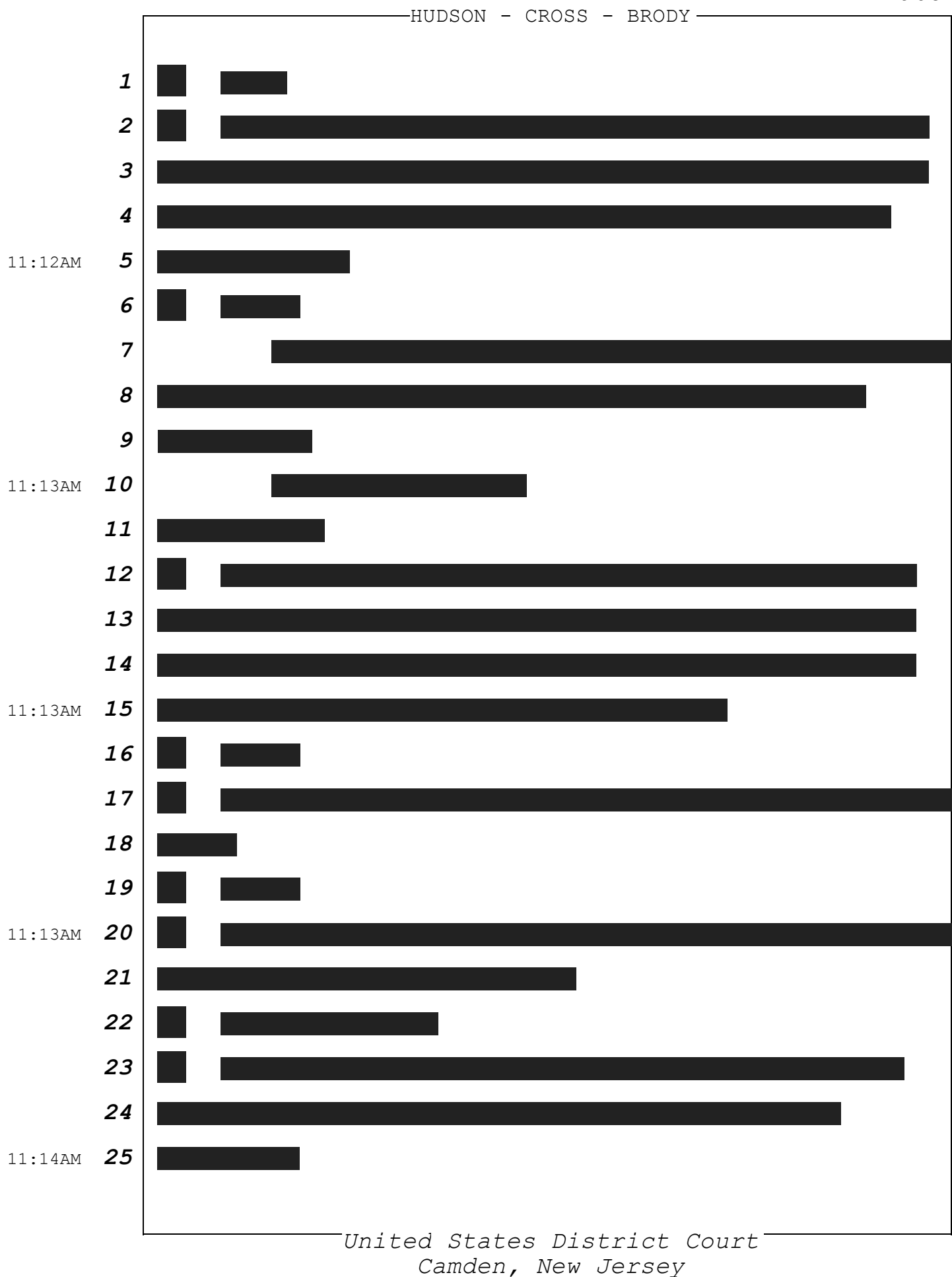


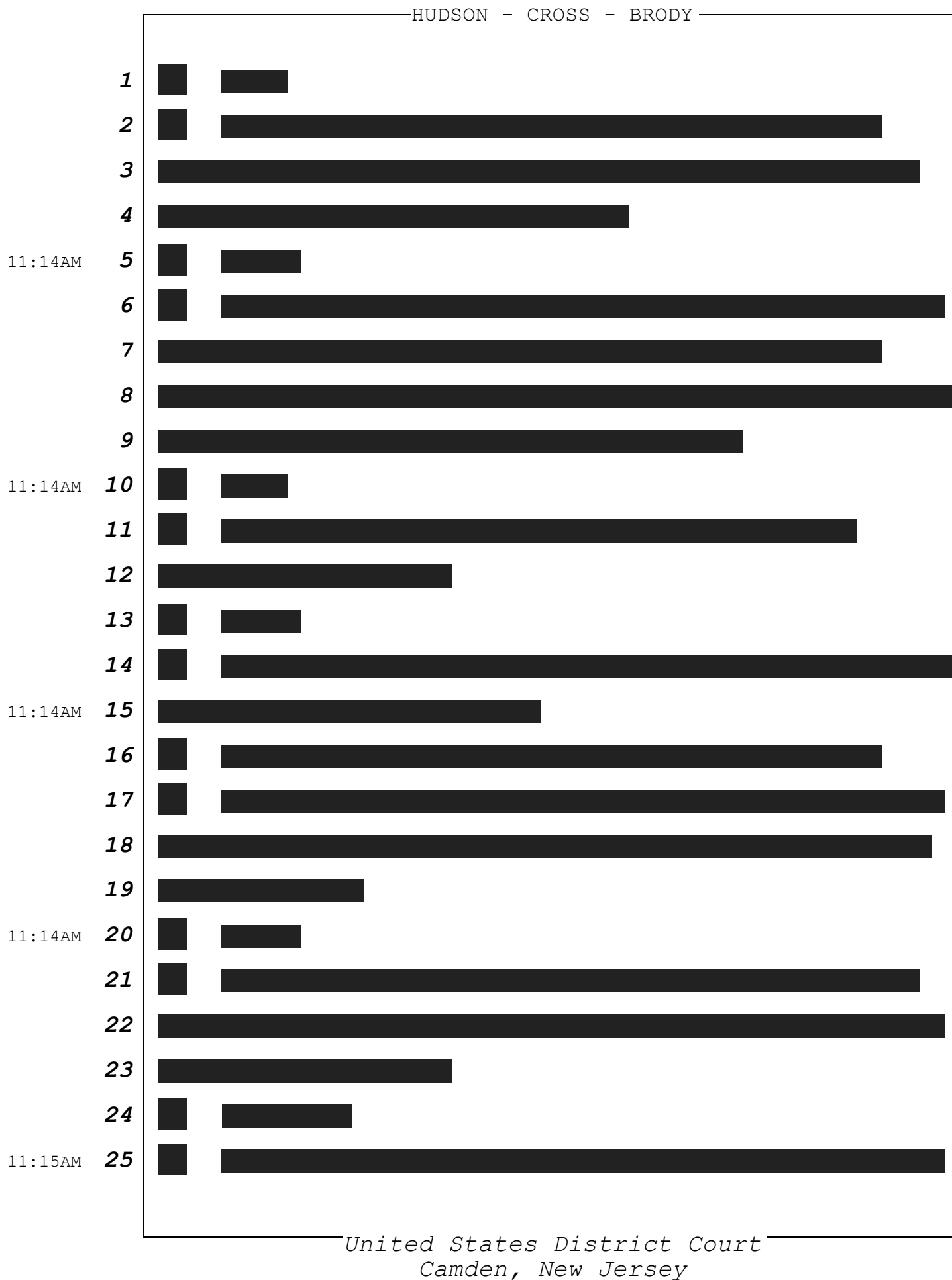


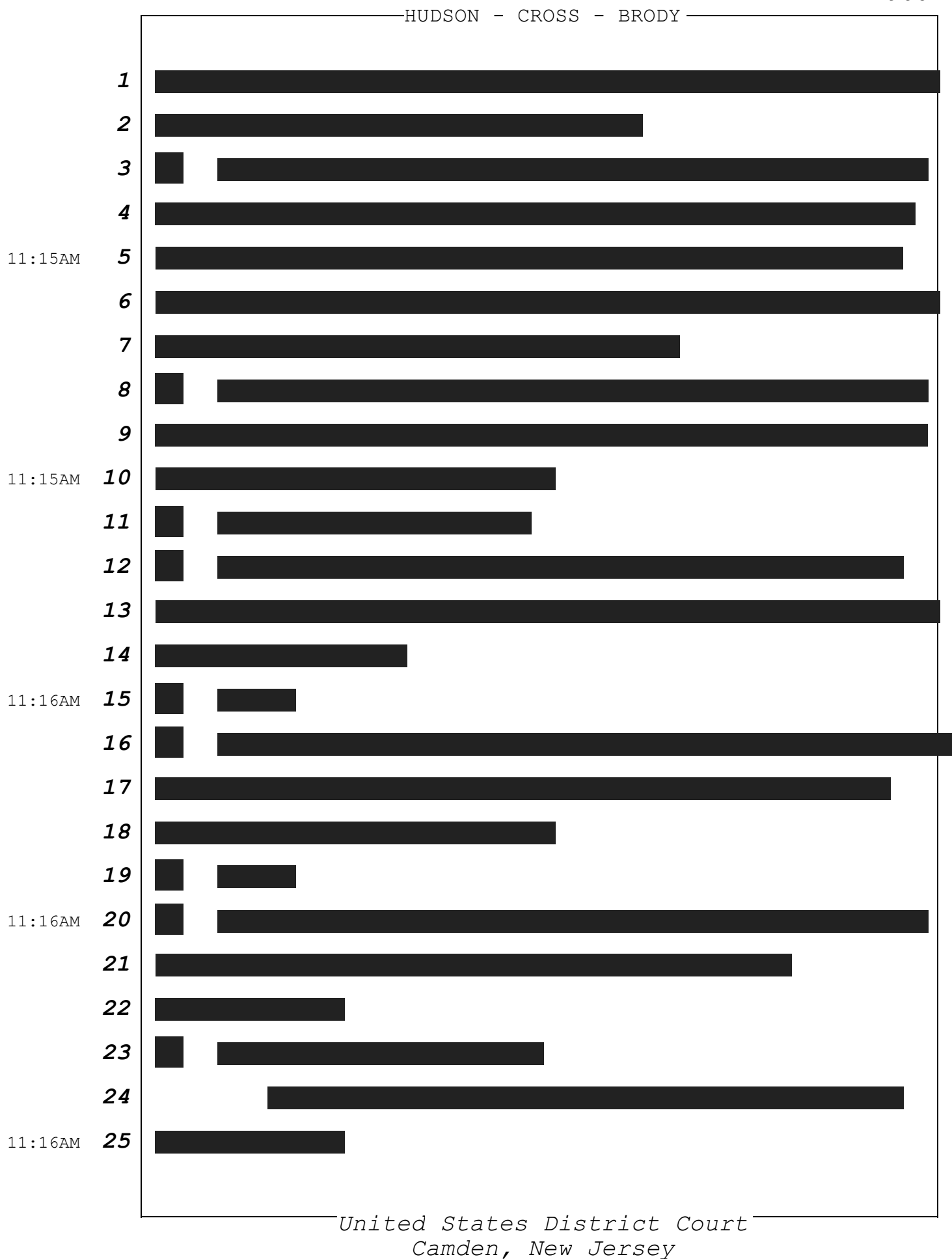












HUDSON - CROSS - BRODY

1

2

3

(By order of the Court, the courtroom was unsealed.)

4

BY MS. BRODY:

11:16AM

5

Q. Now, Mr. Hudson, currently, based on your understanding, sales of Pulmicort Respules® make up about 4 percent of AstraZeneca's total U.S. net sales, correct?

8

A. Yes.

9

Q. That 4 percent figure includes sales of Teva's generic

11:16AM

10

BIS product and the branded Pulmicort® sales, correct?

11

A. Correct.

12

Q. Now, if you were to take the Teva generic BIS sales out

13

of the percentage, the branded Pulmicort Respules® sales would make up about 1.3 or 1.4 percent of the total U.S. net sales,

11:17AM

15

correct?

16

A. Correct.

17

Q. Now, if you consider the Teva generic BIS sales and the

18

branded sales, Pulmicort® sales, based on your math, those

19

sales make up about 2.5 percent of AstraZeneca's total global

11:17AM

20

net sales, correct?

21

A. Yes.

22

Q. And you don't know sitting here today how much of the

23

branded sales make up AstraZeneca's total global net sales, do you?

24

11:17AM

25

A. I would have to calculate it.

—HUDSON - CROSS - BRODY—

1 Q. Have you calculated that percentage?

2 A. No.

3 Q. Now, the current level of investment in terms of
4 promotional strategies for Pulmicort Respules® by AstraZeneca
11:17AM 5 is \$700,000 for the 2014 year, correct?

6 A. I'm sorry. Please repeat that.

7 Q. Of course. The current level of investment in terms of
8 promotional strategies for Pulmicort Respules® at AstraZeneca
9 is \$700,000 for the 2014 year, correct?

11:18AM 10 A. Correct.

11 Q. Now, you don't know how that level of investment compares
12 to the promotional level when Pulmicort Respules® was first
13 marketed in 2000, do you?

14 A. Well, we have -- I'm trying to remember which one it was,
11:18AM 15 but we have some data back to 2000. I can't remember which
16 one it was, the one that you just mentioned.

17 Q. If you take a look to DTX-2044, would that be the
18 document that you're referring to?

19 A. Yes.

11:18AM 20 Q. So, would you agree with me that for promotional
21 expenditures, currently the number at promotions, which is
22 reflected in the line item promotions, correct?

23 A. Yes.

24 Q. That number is substantially lower in 2014 than it was in
11:19AM 25 2000, correct?

HUDSON - CROSS - BRODY

1 A. Yes, correct.

2 Q. Now, the majority of that \$700,000 promotional investment
3 is spent on sampling, correct?

4 A. Correct.

11:19AM 5 Q. And sampling entails simply providing a certain amount of
6 product samples to healthcare providers, correct?

7 A. Correct.

8 Q. Now, the number of employees at AstraZeneca who are
9 currently involved in any way with promotion of Pulmicort
11:19AM 10 Respules® would be approximately 50, correct?

11 A. Somewhere in the region of that, yes.

12 Q. And those approximately 50 people are responsible for
13 organizing the delivery of Pulmicort Respules® samples,
14 correct?

11:20AM 15 A. Correct.

16 Q. And you would refer to those employees responsible for
17 samples as customer service associates, correct?

18 A. Yes, that's one way to describe them, yes.

19 Q. Is it that an acceptable way to describe it?

11:20AM 20 A. Yes.

21 Q. And those customer service associates are responsible for
22 products other than Pulmicort Respules®, correct?

23 A. It depends because there are different tactical
24 campaigns, different in a calendar year. They would focus on
11:20AM 25 individual brands, but they may not focus all year on

—HUDSON - CROSS - BRODY—

1 individual brands. That's why it's hard to be precise.

2 Q. So, sitting here today, do you know if any of those
3 approximately 50 customer service associates are responsible
4 only for Pulmicort Respules®?

11:20AM 5 A. To arrive at the 50, the calculation is, is what I think
6 is attributed during a year for Pulmicort Respules®
7 specifically.

8 Q. And those customer service associates could work on other
9 products throughout the course of a year. Is that fair?

11:21AM 10 A. They could, yes.

11 Q. There is currently no sales force associated with
12 Pulmicort Respules in the United States, correct?

13 A. That's correct.

14 Q. And you do not know how many people are involved in the
11:21AM 15 technical manufacturing of Pulmicort Respules, correct?

16 A. I understand it to be in the region of two to three
17 hundred.

18 Q. And how did you arrive at that number?

19 A. By a question to our operations team.

11:21AM 20 Q. Did you ask that question since your deposition last a
21 Monday on November the 10th?

22 A. Yes.

23 Q. So how many manufacturing people?

24 A. I was told in the region of two to three hundred people.

11:21AM 25 Q. That information was just provided to you in the last

—HUDSON - CROSS - BRODY—

1 week?

2 A. Yes.

3 Q. You do not know what other product, if any, those
4 employees who are involved in this technical manufacture of
11:21AM 5 Pulmicort Respules work on though, correct?

6 A. No.

7 Q. And you understand that Pulmicort Respules is
8 manufactured in the Westboro, Massachusetts AstraZeneca
9 facility, correct?

11:22AM 10 A. Correct.

11 Q. You do not know if AstraZeneca manufactures any other
12 product at that a Westboro facility, correct?

13 A. Correct.

14 Q. And you do not know what other products, if any, the
11:22AM 15 equipment at the Westboro Massachusetts facility can be used
16 to make, correct?

17 A. Correct.

18 Q. Do you understand that AstraZeneca now manufactures a
19 sterile product for sale outside of the United States; is that
11:22AM 20 correct?

21 A. Correct.

22 Q. You do not know though when AstraZeneca started
23 manufacturing that ex-U.S. product as sterile, correct?

24 A. Correct.

11:22AM 25 Q. You do not know where the non-U.S. Pulmicort Respules

—HUDSON - CROSS - BRODY—

1 product is manufactured, correct?

2 A. My understanding it is Sweden and Australia.

3 Q. Did you learn that information since the date of your
4 deposition on November 10th?

11:23AM 5 A. Yes.

6 Q. Do you know if any in that volume of the non-U.S.
7 Pulmicort Respules product is manufactured in the United
8 States.

9 A. If you could please repeat the question.

11:23AM 10 Q. Do you know whether any volume of the non-U.S. Pulmicort
11 Respules product is manufactured outside -- or in the United
12 States?

13 A. No.

14 Q. You don't know if there is volume?

11:23AM 15 A. That's correct.

16 Q. Now, with respect to any alleged irreparable harm
17 AstraZeneca would allegedly suffer as a result of generic BIS
18 entry by any of the defendants it is your opinion that the
19 harm would include any loss in dollar sales AstraZeneca may
11:24AM 20 experience for its Pulmicort Respules product, correct?

21 A. Can you repeat the question, please.

22 Q. Of course. With respect to any alleged irreparable harm
23 AstraZeneca may suffer as a result of a generic BIS entry by
24 any of the defendants, is it your opinion that the harm would
11:24AM 25 include any loss in dollar sales AstraZeneca may experience

—HUDSON - CROSS - BRODY—

1 for its Pulmicort Respules product?

2 A. In part, yes.

3 Q. Now, AstraZeneca has --

4 MS. BRODY: Your Honor, I just want to be sure I'm
11:24AM 5 not stepping into any confidential information.

6 BY MS. BRODY:

7 Q. Now, AstraZeneca has estimated that a multiple generic
8 BIS launch by defendants would result in reduced revenues to
9 AstraZeneca in the amount of approximately \$50 million,

11:25AM 10 correct?

11 A. Correct.

12 MR. ANTHONY: Objection.

13 THE COURT: Basis?

14 MR. ANTHONY: I think that misstates the witness's
11:25AM 15 testimony. Reduced --

16 THE COURT: Well, he agreed with it.

17 MR. ANTHONY: Oh.

18 THE COURT: He agreed with it, so you'll have to save
19 it for redirect.

11:25AM 20 MR. ANTHONY: Very well.

21 BY MS. BRODY:

22 Q. So AstraZeneca has calculated a dollar amount of loss
23 with respect to revenues upon a generic launch by defendants,
24 correct?

11:25AM 25 A. Correct.

—HUDSON - CROSS - BRODY—

1 Q. And with respect to a decrease in royalty payments from
2 Teva, AstraZeneca has also calculated what its estimated
3 losses would be upon generic entry by defendants, correct?

4 A. Correct.

11:25AM

5 Q. And AstraZeneca has calculated the estimated reduction in
6 revenues and royalties upon generic launch in terms of both
7 dollar and unit sales, correct?

8 A. Correct.

11:26AM

9 Q. Now, do you recall discussing supply shortages in your
10 direct testimony?

11 A. Yes.

12 Q. And some of those supply shortages were relevant Teva's
13 generic BIS product, correct?

14 A. Correct.

11:26AM

15 Q. Those supply issues occurred years ago, correct?

16 A. Correct.

17 Q. And by years ago I mean in 2010 to 2011 to your
18 understanding, correct?

19 A. That's my understanding.

11:26AM

20 Q. You have no knowledge sitting here today that Watson
21 would have any issues with the manufacture or supply of its
22 generic BIS product, correct?

23 A. Correct.

11:26AM

24 Q. And you are not aware of any examples where Watson has
25 had any manufacturing issues supplying the market with any of

—HUDSON - CROSS - BRODY—

1 its generic products, correct?

2 A. Correct.

3 Q. At the time Teva experienced supply issues with its BIS
4 product years ago, you were not responsible for AstraZeneca's
11:27AM 5 Pulmicort Respules business, correct?

6 A. Correct.

7 Q. You have not spoken with anyone at Teva concerning any
8 issues it had with supply or manufacture of its BIS product in
9 the past, correct?

11:27AM 10 A. Correct.

11 Q. And you do not know what caused any supply or
12 manufacturing issues that Teva may have experienced in the
13 past with its generic BIS products, correct?

14 A. Correct.

11:27AM 15 Q. And no one at AstraZeneca has been able to identify what
16 caused any supply or manufacturing issues Teva experienced
17 with its BIS product years ago, correct?

18 A. Correct.

19 Q. You are not able to identify any current manufacturing or
11:27AM 20 supply issues Teva is experiencing with respect to its generic
21 BIS product, correct?

22 A. Correct.

23 Q. Now, I believe you talked about confusion by patients in
24 terms of switching products earlier. Do I recall that

11:28AM 25 correctly on your direct exam?

HUDSON - CROSS - BRODY

1 A. Yes.

2 Q. And AstraZeneca became aware of potential confusion based
3 on calls it received from patients, correct?

4 A. Correct.

11:28AM 5 Q. Those calls that AstraZeneca received were received when
6 Teva had its prior supply issues, correct?

7 A. Correct.

8 Q. You have not spoken with any patients who have had their
9 BIS medication switched, have you?

11:28AM 10 A. No.

11 Q. Now, I believe you talked about AstraZeneca's practice of
12 store-housing products; is that correct?

13 A. No, I think I used the expression "buffering."

14 Q. Maybe it was your counsel used the word store-housing and
11:28AM 15 you call it buffering. You agree that AstraZeneca has an
16 inventory buffer for products other than Pulmicort Respules,
17 correct?

18 A. Correct.

19 Q. You also talked about the Toprol product. Do you recall
11:29AM 20 that in your direct testimony?

21 A. Yes.

22 Q. Now, any supply issues with Toprol occurred in past years
23 as well, correct?

24 A. Correct.

11:29AM 25 Q. And any supply issues with the Toprol product were not

—HUDSON - CROSS - BRODY—

1 caused by Watson, correct?

2 A. I don't know specifically.

3 Q. Now, as a global organization, AstraZeneca has
4 experienced employee layoffs, correct?

11:29AM 5 A. Correct.

6 Q. The AstraZeneca U.S. offices have experienced layoffs,
7 correct?

8 A. Correct.

9 Q. And those layoffs have occurred in the last five to
11:29AM 10 seven years, correct?

11 A. Correct.

12 Q. Now, AstraZeneca implemented a restructuring strategy
13 that included various phases of job cuts, correct?

14 A. Correct.

11:29AM 15 Q. Now, when we were talking about the Pulmicort Respules
16 manufacturing employees, you do not have any knowledge of
17 whether any individuals responsible for the Pulmicort Respules
18 brand product on the manufacturing line could be transferred
19 to another product line, correct?

11:30AM 20 A. That's correct.

21 Q. Now, with respect to the approximate 800 people you
22 testified about whom AstraZeneca would need to lay off if
23 additional generics entered, you would approximate the dollar
24 amount tied to each individual as approximately \$150,000,

11:30AM 25 correct?

—HUDSON - CROSS - BRODY—

1 A. No. It's a range. If that's an average, then possibly,
2 but it depends on the role the person performed.

3 Q. Would you agree that the range would be approximately
4 from \$150,000 to \$250,000?

11:30AM 5 A. I think the range is wider, but the average would be
6 about right.

7 Q. But there is a dollar amount of range that you would tie
8 to the 800 employees that you testified AstraZeneca would need
9 to lay off, correct?

11:30AM 10 A. I have a working assumption around the average cost of
11 manpower in general across the business and, therefore, can
12 make a calculation.

13 Q. And that calculation could average around \$150,000 an
14 employee.

11:31AM 15 A. Yes.

16 Q. Now, in arriving at the 800 count employment layoff, you
17 have taken into account certain assumptions, correct?

18 A. Correct.

19 Q. The position that AstraZeneca would need to lay off 800
11:31AM 20 employees in the event of a generic launch by defendants
21 assumes, for example, that there is no other income
22 experienced by AstraZeneca to make up the loss of the
23 Pulmicort Respules business, correct?

24 A. Correct.

11:31AM 25 Q. Now, AstraZeneca does not have any analysis relating

HUDSON - CROSS - BRODY

1 specifically to Pulmicort Respules that shows how it arrived
2 at the 800 head count reduction about which you testified,
3 correct?

11:32AM 4 A. The -- we routinely work scenarios of if profit was
5 affected, what the implications would be. We are -- it can be
6 from any part of the portfolio, but the question is what would
7 be the financial implications to protect profit in the
8 organization.

11:32AM 9 Q. AstraZeneca does not have any analysis relating
10 specifically to Pulmicort Respules that shows how it arrives
11 at the 800 head count reduction about which you testified,
12 correct?

11:32AM 13 A. So we routinely work through what scenarios would be
14 required with loss revenue. We understand what the loss
15 revenue would be with respules and we can make an
16 approximation of the number of people that would have to leave
17 the organization.

11:33AM 18 Q. Other than a general analysis that works through
19 scenarios, you have not seen any scenarios specific to
20 Pulmicort Respules, have you?

21 A. We don't routinely scenario per medicine, we routinely
22 scenario based on the impact on the P&L and, therefore, I
23 would expect the scenarios that we have in place to suit
24 Pulmicort Respules specifically.

11:33AM 25 Q. But there is no scenario specific to Pulmicort Respules

HUDSON - CROSS - BRODY

1 that AstraZeneca has prepared, correct?

2 A. Or any other brand.

3 Q. As of today, AstraZeneca does not know if any of the 800
4 individuals it claims it will need to lay off could work in
11:33AM 5 any other part of the company, correct?

6 A. Well, you don't lay people off to reemploy them. The
7 math doesn't add up from a profit perspective. So unless they
8 were filling an existing vacancy that had budget attributed to
9 it, the people are on incremental costs that would have to be
11:34AM 10 found, therefore it is unlikely they would be reemployed.

11 Q. But it is possible that's 800 individuals that you
12 testified about could fill vacancies within the company
13 without being laid off, correct?

14 A. I think, as you pointed out already, we're restructuring
11:34AM 15 and becoming smaller, so I think it's highly unlikely.

16 Q. And that restructuring and becoming smaller does not --
17 was not caused specifically by generic entry into the BIS
18 market, correct?

19 A. We haven't -- there isn't a generic entry.

11:34AM 20 Q. The global restructuring that you've testified about was
21 not a result specifically of anticipated generic entry into
22 the BIS market, correct?

23 THE COURT: The question is anticipated.

24 THE WITNESS: Yeah, it does. There is a long range
11:35AM 25 plan of which we calculate what our revenues are, but

HUDSON - CROSS - BRODY

1 restructuring that you mentioned earlier are part of an
2 ongoing transformation process.

3 BY MS. BRODY:

4 Q. Now, you have not identified any evidence that

11:35AM 5 AstraZeneca has laid off 800 employees every time it has lost
6 \$300 or \$400 million in product sales, have you?

7 A. We haven't presented any of that.

8 Q. Now, I want to talk a little more about the global
9 restructuring layoffs you testified AstraZeneca has

11:35AM 10 experienced in the last several years. Could you please turn
11 to DTX-2195 in your binder that I provided you?

12 A. Yes.

13 Q. Are you there?

14 A. Yup.

11:35AM 15 Q. You've seen this document before, correct?

16 A. Yes.

17 Q. This is an article entitled "AstraZeneca to Layoff 135 in
18 Westboro" dated May 19, 2011, correct?

19 A. Correct.

11:36AM 20 Q. And you testified earlier that the Westboro facility is
21 the same facility where you understand AstraZeneca
22 manufactures the Pulmicort Respules product, correct?

23 A. Correct.

11:36AM 24 Q. And this article states in the second sentence, "The
25 layoff is part of a worldwide restructuring of the UK-based

—HUDSON - CROSS - BRODY—

1 pharmaceutical company announced last year, which will include
2 a total of 8,550 layoffs. The 2010 downsizing followed a
3 first round of restructuring in 2009 which led to 15,000
4 layoffs, including 113 at the same Westboro facility which
11:36AM 5 were announced in September 2009." Correct.

6 A. Correct.

7 Q. Now, this article goes onto state in the third paragraph,
8 "The Westboro facility provides supply and packaging for a
9 number of AstraZeneca's sterile injectable, topical and
11:36AM 10 respiratory products, including allergy drug Rhinocort Aqua
11 and asthma treatment Pulmicort Respules." Correct?

12 A. Correct.

13 Q. Do you know if the active ingredient in Rhinocort Aqua is
14 budesonide?

11:37AM 15 A. Yes.

16 Q. And you understand the active ingredient in Pulmicort
17 Respules is budesonide?

18 A. Yes.

19 Q. Now, this article does not mention anything about the
11:37AM 20 noted layoffs being a result of anticipated generic launch of
21 BIS or potential competition in that market, correct?

22 A. Correct.

23 MS. BRODY: Your Honor, we move to admit DTX-2195 in
24 evidence.

11:37AM 25 MR. ANTHONY: No objection.

—HUDSON - CROSS - BRODY—

1 THE COURT: In evidence.

2 (PLAINTIFF EXHIBIT DTX-2195 WAS RECEIVED IN EVIDENCE)

3 BY MS. BRODY:

4 Q. Would you please turn to DTX-3603 in the binder I

11:37AM 5 provided you. And you've seen this document before too,
6 correct?

7 A. Yes.

8 Q. That's an AstraZeneca press release dated February 2,

9 2012, entitled "AstraZeneca's new restructuring initiative to

11:38AM 10 drive productivity and support innovation." Correct?

11 A. Correct.

12 Q. AstraZeneca prepares presence releases in the ordinary

13 course of business, correct?

14 A. Correct.

11:38AM 15 Q. Now, if you look to the first paragraph on the first page

16 of this document, it states, "In conjunction with the

17 publication of its full year 2011 results earlier today,

18 AstraZeneca announced new restructuring initiatives designed

19 to improve productivity and strengthen the company's

11:38AM 20 commercial, operations and research and development

21 capabilities." Correct?

22 A. Correct.

23 Q. Now, if you looked at the second paragraph of this press

24 release on page 1, it states, "This new programme is expected

11:38AM 25 to deliver an estimated 1.6 billion in annual benefits by the

—HUDSON - CROSS - BRODY—

1 end of 2014, at an estimated total cost of \$2.1 billion.

2 AstraZeneca expects that this restructuring programme will

3 affect approximately 73,000 positions." Correct?

4 A. Correct.

11:39AM 5 Q. And if you turn to the second page of this press release,

6 looking to the next to last paragraph on this page, it states,

7 "The implementation of this new model will lead to a

8 significant reduction in employee numbers and the end of R&D

9 activity at two sites that are focused on neuroscience."

11:39AM 10 Correct.

11 A. Correct.

12 Q. Now, as part of this restructuring program announced in

13 AstraZeneca's February 2012 press release there were layoffs

14 of significant proportion. Would you agree?

11:39AM 15 A. Correct.

16 MS. BRODY: Your Honor, we move to admit DTX-3603

17 into evidence.

18 THE COURT: Any objection?

19 MR. ANTHONY: No objection.

11:39AM 20 THE COURT: In evidence.

21 (DEFENDANT EXHIBIT DTX-3603 WAS RECEIVED IN EVIDENCE)

22 BY MS. BRODY:

23 Q. Mr. Hudson, could you please turn to DTX-2179 in the

24 binder I provided to you. You've seen this document before,

11:40AM 25 correct?

—HUDSON - CROSS - BRODY—

1 A. Yes.

2 Q. This is an AstraZeneca press release dated March 21,
3 2013, entitled "AstraZeneca Outlines Strategy to Return to
4 Growth and Achieve Scientific Leadership." Correct?

11:40AM 5 A. Correct.

6 Q. In the first paragraph on page one of this press release
7 it states, "AstraZeneca will today outline its strategy to
8 return to growth and achieve scientific leadership." Correct?

9 A. Correct.

11:40AM 10 Q. Now, if you looked at page four of this press release in
11 the fourth paragraph on this page it states, "We are combining
12 this SG&A restructuring with two previously announced
13 programmes. These comprise the head count reduction of 1,600
14 related to the proposed R&D footprint changes announced on 18
11:41AM 15 March 2013, and the balance of Phase 3 restructuring programme
16 announced in February 2012 which amounts to 1,150 roles. The
17 total combined Phase 4 programme entails an estimated global
18 head count reduction of about 5,050 over the 2013 to 2016
19 period." Correct?

11:41AM 20 A. Correct.

21 MS. BRODY: Your Honor, we move to admit DTX-2179
22 into evidence.

23 MR. ANTHONY: No objection.

24 THE COURT: In evidence.

11:41AM 25 (DEFENDANT EXHIBIT DTX-2179 WAS RECEIVED IN EVIDENCE)

HUDSON - CROSS - BRODY

1 BY MS. BRODY:

2 Q. Could you please turn to DTX-2197 in your binder that I
3 handed to you. And you've seen this document before, correct?

4 A. Yes.

11:41AM 5 Q. There is an article dated February 6, 2014, entitled
6 "Updated: AstraZeneca steps up its global restructuring with
7 550 new job cuts." Correct?

8 A. Correct.

9 Q. And the first paragraph on the first page of that article
11:41AM 10 it states, "AstraZeneca has upped its job cutting toll to
11 5,600. After announcing 5,050 layoffs last year, the company
12 disclosed today that it is adding another 550 to the mix.

13 That brings the total workforce cuts to 5,600 jobs. " Correct?

14 A. Correct.

11:42AM 15 Q. And if you look to the next to last paragraph on the
16 first page of this article in the last sentence do you see
17 that it states, "AZ's restructuring -- Phases 1 to 3 --
18 claimed more than 20,000 jobs." Correct?

19 A. Correct.

11:42AM 20 MS. BRODY: Your Honor, we move to admit DTX-2197
21 into evidence.

22 THE COURT: Any objection?

23 MR. ANTHONY: No objection.

24 THE COURT: In evidence.

11:42AM 25 (DEFENDANT EXHIBIT DTX-2197 WAS RECEIVED IN EVIDENCE)

HUDSON - CROSS - BRODY

1 BY MS. BRODY:

2 Q. Now, based on feedback of an AstraZeneca internal survey
3 conducted, AstraZeneca employee engagement and morale declined
4 in 2012. Correct?

11:42AM 5 A. That's my recollection, yes.

6 Q. In reviewing or seeing any of those employee surveys that
7 showed an impact on morale and engagement, you did not see any
8 specific comments that this impact was the result of generic
9 competition or potential generic competition in the Pulmicort

11:43AM 10 Respules market, correct.

11 A. That's correct.

12 Q. Now, historically AstraZeneca has spent approximately 14
13 to 19 percent of it's total annual revenues on R&D, correct?

14 A. Correct.

11:43AM 15 Q. And that figure would be accurate currently as well,
16 correct?

17 A. Correct.

18 Q. Now, Pulmicort Respules -- strike that. You mentioned
19 earlier, you used the phrase I believe "contribution

11:43AM 20 positive." Do you recall that?

21 A. Yes.

22 Q. And Pulmicort Respules is not the only product that is
23 contribution positive for AstraZeneca, correct?

24 A. That's correct.

11:43AM 25 Q. You don't know how many contribution positive products

—HUDSON - CROSS - BRODY—

1 AstraZeneca currently sells worldwide, correct?

2 A. I don't account for the state of the launch phases in
3 every market, no.

4 Q. So is it correct that you can not know how many
5 contributions positive products Astra currently sells
6 worldwide?

7 A. It's correct that I would have to go across every product
8 in over a hundred countries and make a decision based on their
9 individual P&L and I have not seen that information, so I
10 can't make that comment.

11 Q. Now, AstraZeneca has taken out loans to pay for strategic
12 transactions such as that it recently is undertook with
13 Balmoral, correct?

14 A. Correct.

15 Q. Now, if you could please turn to DTX-3704 in the binder I
16 provided you. Do you recognize this document as "AstraZeneca
17 PLC's third quarter and nine months results 2014"? And this
18 is dated November 6, 2014.

19 A. Correct.

20 Q. This is a document AstraZeneca prepares in the normal
21 course of business; is that correct?

22 A. Correct.

23 MS. BRODY: Your Honor, I would move to admit
24 DTX-3704 into evidence.

25 MR. ANTHONY: No objection.

HUDSON - CROSS - BRODY

1 THE COURT: Okay. In evidence.

2 (DEFENDANT EXHIBIT DTX-3704 WAS RECEIVED IN EVIDENCE)

3 BY MS. BRODY:

4 Q. Now, please turn to page 19 of this financial statement.

11:45AM 5 If you look at the top, do you see the heading "Assets"?

6 A. Yes.

7 Q. And do you see the subheading "Current assets" which is
8 in the second box there?

9 A. Yes.

11:45AM 10 Q. Do you see the line item Cash and cash equivalents?"

11 A. Yes.

12 Q. Looking across that row, as of September 30th, 2014,
13 AstraZeneca had cash and cash equivalents, according to this
14 financial disclosure, in the amount of \$5 billion 146 million,
11:46AM 15 correct?

16 A. Correct.

17 Q. Now, you have not done a calculation to determine what
18 impact, if any, a loss in the range of 300 to 400 million
19 dollars would have on AstraZeneca's core earnings per share
11:46AM 20 calculation, correct?

21 A. That's correct.

22 Q. You're not sure what impact, if any, loss in the range of
23 300 million to 400 million would have on AstraZeneca's core
24 earnings per share, correct?

11:47AM 25 A. Correct.

—HUDSON - CROSS - BRODY—

1 Q. As far as mid year 2014, do you know if the core earnings
2 per share is higher than predicted or forecasted at
3 AstraZeneca?

4 A. It's a little behind guidance.

11:47AM 5 Q. I'll ask you again.

6 As far as middle of the year, do you know if the core
7 EPS in 2014, by mid 2014, is higher than predicted or
8 forecasted?

9 A. It's broadly in line with expectations.

11:47AM 10 Q. Do you recall you were deposed on November 10th, 2014 in
11 this matter?

12 A. Yes.

13 Q. Can you -- there should be a transcript at the end of the
14 binder I handed you.

11:47AM 15 A. Yes, I can find it.

16 Q. And if you could look to -- I'll come back to this.

17 Now, AstraZeneca has made calculations as to the
18 financial loss it alleges it would incur as a result of the
19 pricing crash you testified to, correct?

11:48AM 20 A. Correct.

21 Q. And AstraZeneca routinely makes that calculation,
22 correct?

23 A. Correct.

24 Q. And AstraZeneca routinely makes that calculation by
11:48AM 25 looking at the analogs in the marketplace, correct?

HUDSON - CROSS - BRODY

1 A. Correct.

2 Q. AstraZeneca could forecast a potential loss -- strike
3 that.

4 AstraZeneca can forecast a potential loss in the event
5 of a generic launch and was pulled from the market, correct?

11:49AM

6 A. Could you repeat the question, please?

7 Q. Of course.

8 AstraZeneca could forecast a potential loss in the
9 event of a generic launch and was pulled from the market,

11:49AM

10 correct?

11 A. A loss to revenue, yes.

12 Q. Now, I believe you talked briefly about Medicaid in your
13 direct examination, correct?

14 A. Correct.

11:49AM

15 Q. AstraZeneca has Medicaid contracts for the sale of
16 Pulmicort Respules, correct?

17 A. Correct.

18 Q. AstraZeneca's net sales numbers for Medicaid
19 include sales -- strike that.

11:49AM

20 AstraZeneca's net sales numbers include sales to
21 Medicaid, correct?

22 A. Correct.

23 Q. And I believe you testified that many of AstraZeneca's
24 Medicaid contracts are loss making, correct?

11:50AM

25 A. I don't think I said many. I said I think in this

HUDSON - CROSS - BRODY

1 situation, yes.

2 Q. Now, in past years AstraZeneca did make a profit on
3 Medicaid contracts, correct, to your understanding?

4 A. I haven't looked at them.

11:50AM 5 Q. Now, you do not have any understanding as to whether Teva
6 has sought to supply Medicaid patients with its generic BIS
7 product, correct?

8 A. Correct.

9 MS. BRODY: Your Honor, I'm going to have a brief
11:50AM 10 section that talks about royalties, but I think I'll try to
11 save it to the end.

12 THE COURT: Okay. Thank you.

13 MS. BRODY: If that's acceptable to you.

14 THE COURT: Okay. Thank you.

11:50AM 15 BY MS. BRODY:

16 Q. Now, the irreparable harms about which you testified are
17 based on the loss of royalties and revenues in the range of
18 approximately \$300 million dollars annually, correct?

19 A. Correct.

11:51AM 20 Q. Have you evaluated what irreparable harm, if any,
21 AstraZeneca would suffer if the loss is in the range of 55
22 million dollars?

23 A. I'm not sure why that would be done.

24 Q. So you haven't done that evaluation, correct?

11:51AM 25 A. The relative loss and irreparable harm on 50 million

HUDSON - CROSS - BRODY

1 dollars.

2 Q. 55 million dollars.

3 A. You know, using -- you could -- that would still be a
4 reduction in investment in our organization and both in R&D,
11:51AM 5 it would just be quantifiably smaller.

6 Q. Sitting here today you have not done any evaluation or
7 detailed analysis as to what irreparable harm, if any,
8 AstraZeneca would suffer if a loss was in the range of 55
9 million dollars, correct?

11:52AM 10 A. So the loss from where to where?

11 The loss from 300 to 250 or are you talking if the
12 revenue was 50?

13 Q. When you spoke of the loss of 300 million dollars, was
14 that down from approximately \$400 million?

11:52AM 15 A. Correct.

16 Q. So if you take -- if you consider a loss from \$400
17 million to \$55 million, sitting here today, have you done any
18 analysis concerning what harm, if any, AstraZeneca would
19 suffer in the event of that type of --

11:52AM 20 A. So, in principle that's the loss we're talking about.

21 Q. During your direct examination, though, your irreparable
22 harm about which you testified were based on a loss in the
23 range of approximately \$300 million annually, correct?

24 A. Well, as I said, the range of sales or contribution is
11:52AM 25 somewhere between three and 400 million dollars depending on

HUDSON - CROSS - BRODY

1 how 2014 plays out.

2 I think I also said that sales would fall to
3 something around about 50 million dollars. So the irreparable
4 harm calculation was the impact of the drop from one to the
5 other.

11:53AM

6 I'm not understanding your question at all.

7 THE COURT: So if it turned out, you did the
8 calculations, and it turned out that it was not a \$300 million
9 drop, but a \$55 million drop, for example, what would -- did
10 you do any irreparable injury analysis? Could the company
11 absorb that loss?

11:53AM

12 THE WITNESS: Well, our irreparable harm calculation
13 is partly based on royalty. And you don't get the chance to
14 make that calculation because the royalty changes immediately
15 and then the reinvestment of that dollar is not possible.

11:53AM

16 If it dropped from \$350 to \$300 which is what I think
17 you're saying, that would be -- there would be less to invest,
18 but I'm presuming that loss would be because of normal course
19 of business, not because of generic entries.

11:54AM

20 I'm sorry if I'm getting confused.

21 BY MS. BRODY:

22 Q. If a contribution gap of 55 million dollars exists, have
23 you calculated how many employees that would equate to?

24 A. Well, as I said earlier, we routinely look at what we'd
25 have to reduce manpower to cover a general contribution gap.

11:54AM

—HUDSON - CROSS - BRODY—

1 And, you know, 50 million dollars would be the equivalent of
2 an average of 150 thousand dollars -- divided by an average of
3 150 thousand dollars on an annualized head count.

11:54AM 4 Q. So the head count, if there was a 55 million dollar
5 contribution gap as opposed to a 300 million dollar
6 contribution gap would be less than eight hundred employees,
7 correct?

8 A. Correct.

11:55AM 9 Q. Now, do you understand that AstraZeneca's R&D budget
10 comes out of its total revenues?

11 A. Correct.

12 Q. And I want to take a look at that.

13 If we could turn -- there is actually a binder that I
14 believe says AstraZeneca annual reports.

11:55AM 15 A. Sure.

16 Q. The larger binder that I provided you.

17 Could you take a look to DTX 3706 in that binder,
18 please.

19 A. Yes, I'm wrestling with the binder.

11:55AM 20 Q. Documents don't always cooperate.

21 Do you recognize this as AstraZeneca's annual report
22 and Form 20F information from 2013?

23 A. Yes.

11:55AM 24 Q. And if you could take a look to -- I'm going to refer you
25 to the numbers that are bates labeled on the bottom right-hand

HUDSON - CROSS - BRODY

1 corner, sir. It's 195 of 240.

2 A. Yes.

3 Q. And do you see that this page requests group financial
4 record?

11:56AM 5 A. Hold on. I think I'm on the wrong page. I apologize.

6 Yes.

7 Q. And is the page you're looking at the same as what's
8 reflected on the screen, sir?

9 A. Yes.

11:56AM 10 Q. And that's page 195 of 240.

11 Now, if you could take a look to the first line item
12 under revenues and profits. Do you see where it says revenue?

13 A. Yes.

14 Q. And for 2013 that revenue line equals \$25 billion 711

11:56AM 15 million, correct?

16 A. Correct.

17 Q. Now, do you understand if -- strike that.

18 If you look down, then, to the line item, research and
19 development expense?

11:56AM 20 A. Yes.

21 Q. And that number is reduced from revenues, correct?

22 A. Yes.

23 MS. BRODY: Your Honor, we move to admit DTX 3706
24 into evidence.

11:57AM 25 THE COURT: Any objection?

HUDSON - CROSS - BRODY

1 MR. ANTHONY: No objection.

2 THE COURT: In evidence.

3 (DEFENDANT EXHIBIT DTX-3706 WAS RECEIVED IN EVIDENCE)

4 (Exhibit DTX 3706 is received into evidence)

11:57AM 5 MS. BRODY: Your Honor, I believe, I may have
6 information that's confidential.

7 May I have a moment?

8 THE COURT: Yes.

9 MS. BRODY: Thank you.

11:57AM 10 THE COURT: I don't think there is anyone in the room
11 who shouldn't be, if I were to seal the courtroom.

12 Do you wish for me to seal it?

13 MS. BRODY: Your Honor, I have a few questions about
14 something that does not need to be sealed and then we will be
11:58AM 15 talking briefly about the royalty issue again.

16 THE COURT: Okay. Let me know.

17 MS. BRODY: Thank you, your Honor.

18 BY MS. BRODY:

11:58AM 19 Q. Mr. Hudson, I believe you testified that you reviewed the
20 declarations that were submitted in this litigation by Ms.
21 Palczuk, is that correct?

22 A. I read it, yes.

23 Q. In your direct testimony, I believe if I heard you
24 correctly, you testified that if there was a launch of generic
11:58AM 25 BIS by defendants, that would force budget reductions for R&D

—HUDSON - CROSS - BRODY—

1 by an amount up to 400 million dollars.

2 Did I hear you correctly?

3 A. That would be the lost profit that we've been unable to
4 reinvest in the company and depending on which R&D projects,
11:59AM 5 they have slightly different values, but that would be the
6 intention, yes.

7 Q. Now, do you recall that Ms. Palczuk previously stated in
8 her declaration that revenue loss from defendants' premature
9 launch of generic BIS would force budget reductions for
11:59AM 10 corporate research and development by an amount up to 150
11 million?

12 A. Correct, yes.

13 Q. And do you agree with that statement?

14 A. Well, I have no reason to challenge the views of other
11:59AM 15 people at all.

16 In my position, I may make a decision to invest even
17 greater into R&D. Out of the four hundred, as I mentioned
18 earlier, some investment is attributed to maintaining
19 commercial launches as to R&D. And the decision on which way
12:00PM 20 to play those depends on what revenue is available at the
21 time.

22 Q. So is it fair to say that different individuals within
23 AstraZeneca may have a different position on how much R&D
24 would need to be cut?

12:00PM 25 A. Well, I think there is two things.

HUDSON - CROSS - BRODY

1 I think, firstly, I'm the president of the U.S.

2 business, so my view generally would be slightly more macro

3 into what's required as an organization.

4 And secondly, I think, and I may not be remembering

12:00PM 5 this correctly from Ms. Palczuk's declaration, but she

6 mentioned the job losses and the R&D combined which equates to

7 roughly the amount of outstanding contribution.

8 How that's balanced would be ultimately mine and the

9 executive team's decision.

12:01PM 10 Q. Now, do you know which legal or corporate entity of

11 AstraZeneca directly profits from the sales of Pulmicort

12 Respules in the United States?

13 A. I just want to try to make sure I get this right.

14 So the revenues -- the other income is attributed on

12:01PM 15 my local P&L. Group and PLC reconcile it through different

16 corporate finance strategies, depending on somewhere between

17 Sweden and the UK.

18 Q. Do you know which legal or corporate entity of

19 AstraZeneca directly profits from the sales of Pulmicort

12:01PM 20 Respules in the U.S. market?

21 A. It depends what you mean by profits.

22 Q. Can you take a look to your deposition transcript that's

23 in the back of your binder, please.

24 A. Yes.

12:01PM 25 Q. If you could look to page 79.

HUDSON - CROSS - BRODY

1 Again, I believe you confirmed earlier, you were
2 deposed in this matter on November 10th, 2014, correct?

3 A. Yes.

4 Q. If you could take a look to page 79, lines 9 to 17 where
5 you were asked these questions and did you provide these
6 answers?

7 QUESTION: Do you know which legal or corporate
8 entity of AstraZeneca directly profits from the sales of
9 Pulmicort Respules in the U.S. market?

10 Answer: That's a group finance question. It would
11 have to be answered by group finance.

12 Question: So you don't know?

13 Answer: No.

14 Were you asked those questions and did you give those
15 answers?

16 MR. ANTHONY: Objection. It's not a factual
17 inconsistency.

18 THE COURT: Sustained.

19 BY MS. BRODY:

20 Q. Now, the royalties received from Teva is other income
21 that is booked through AstraZeneca PLC, correct?

22 A. Ultimately, yes.

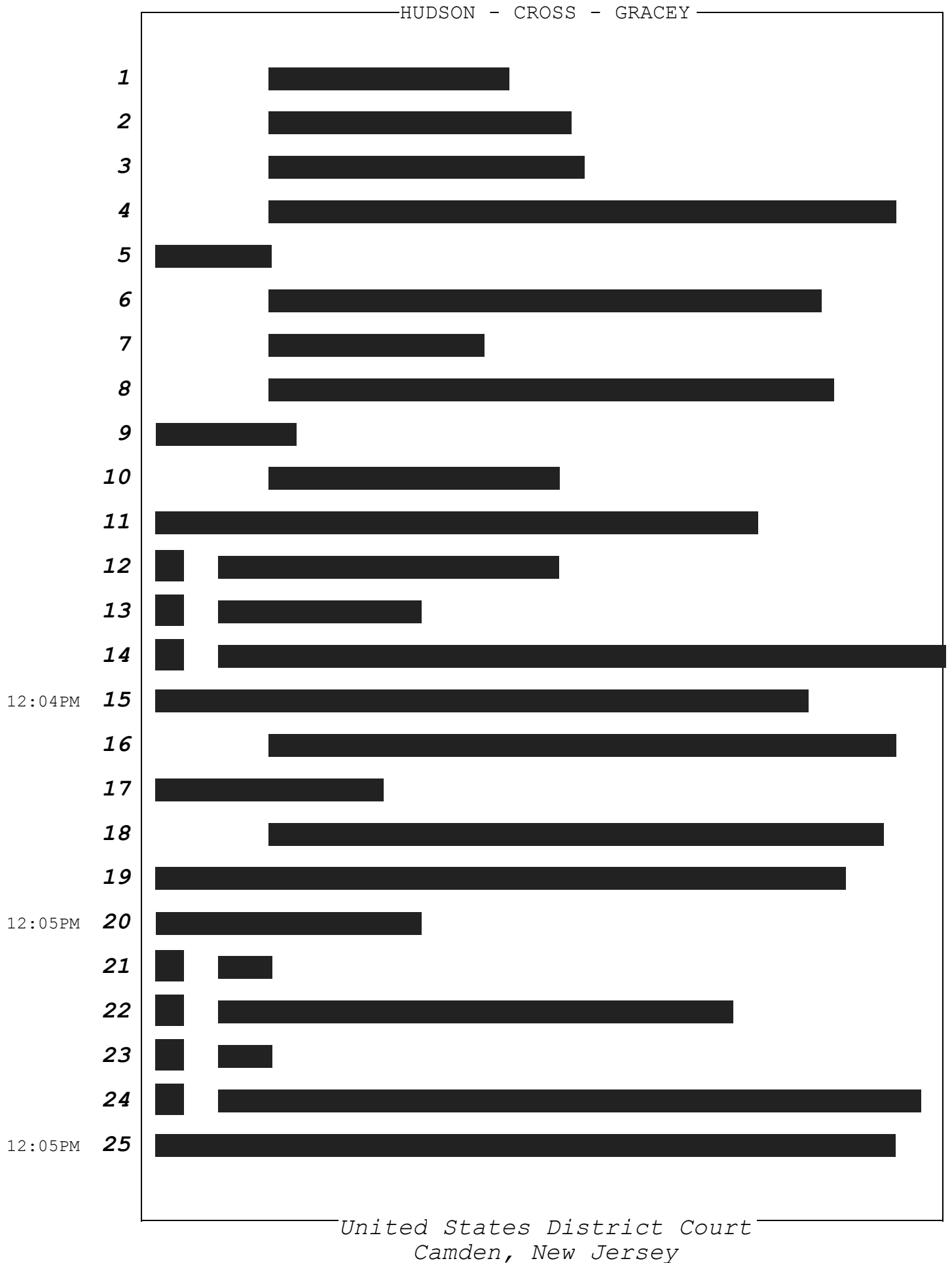
23 MS. BRODY: Your Honor, I do have a few questions
24 that will require sealing the courtroom.

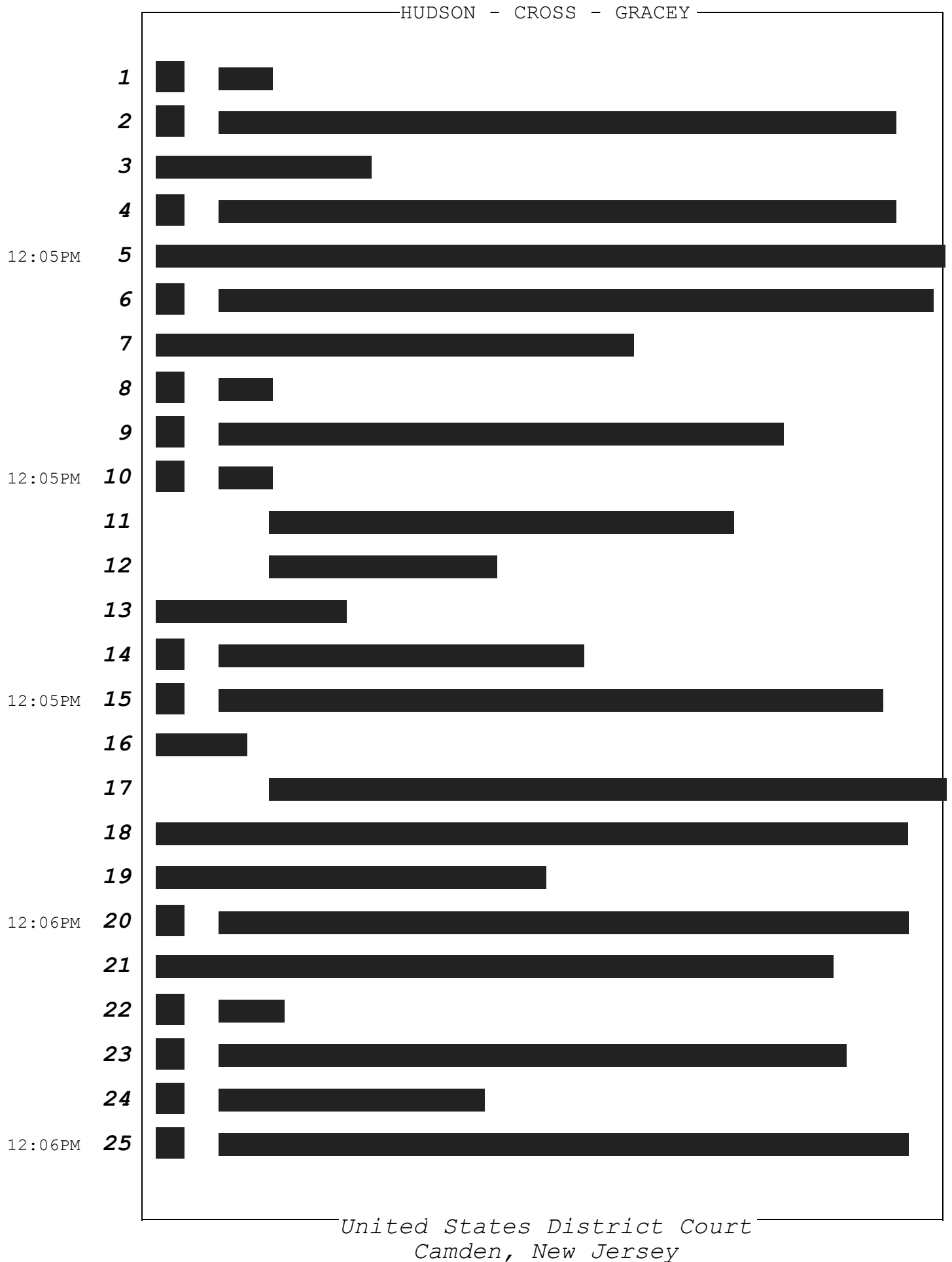
25 THE COURT: Okay. So the courtroom will be sealed.

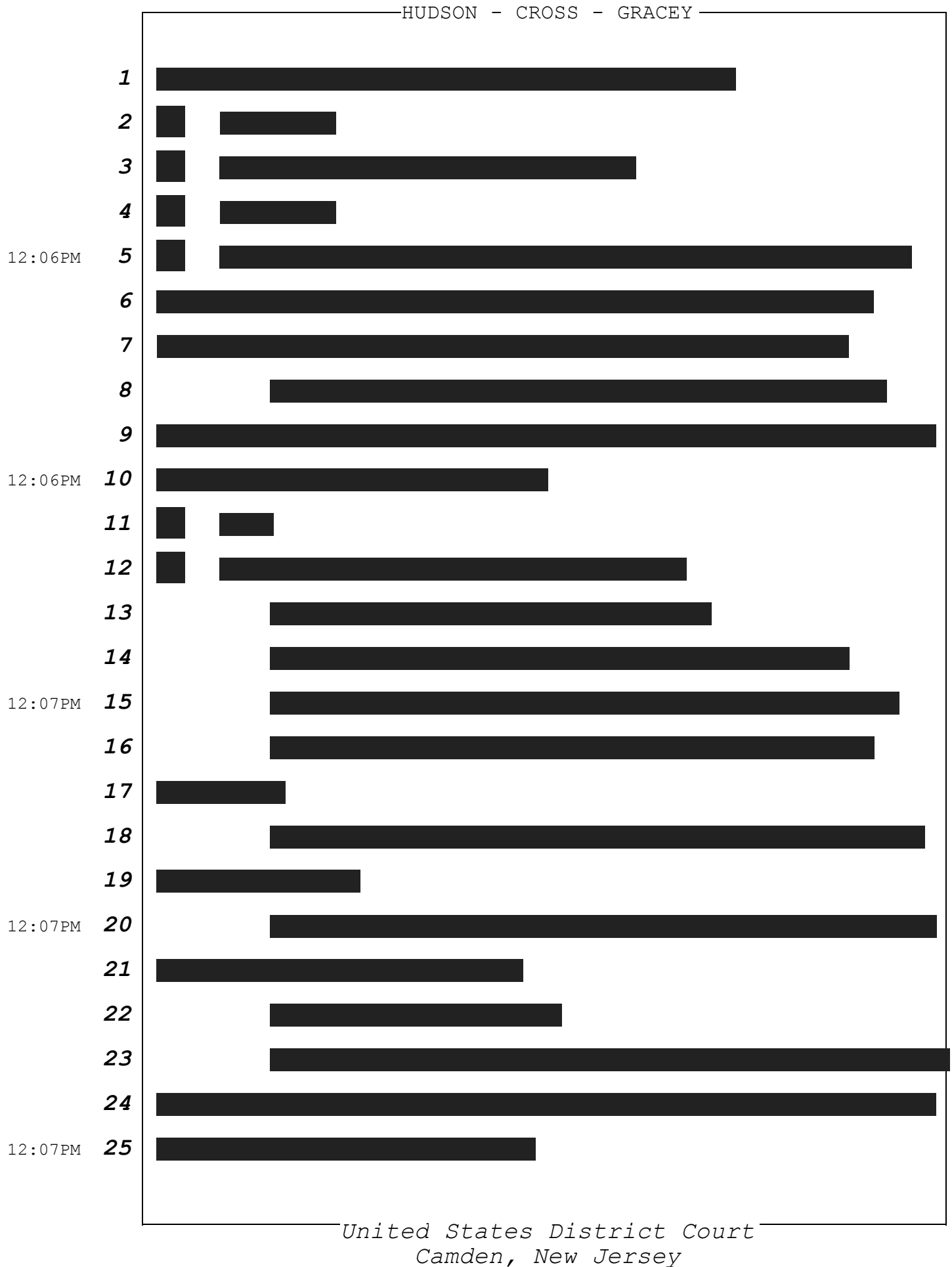
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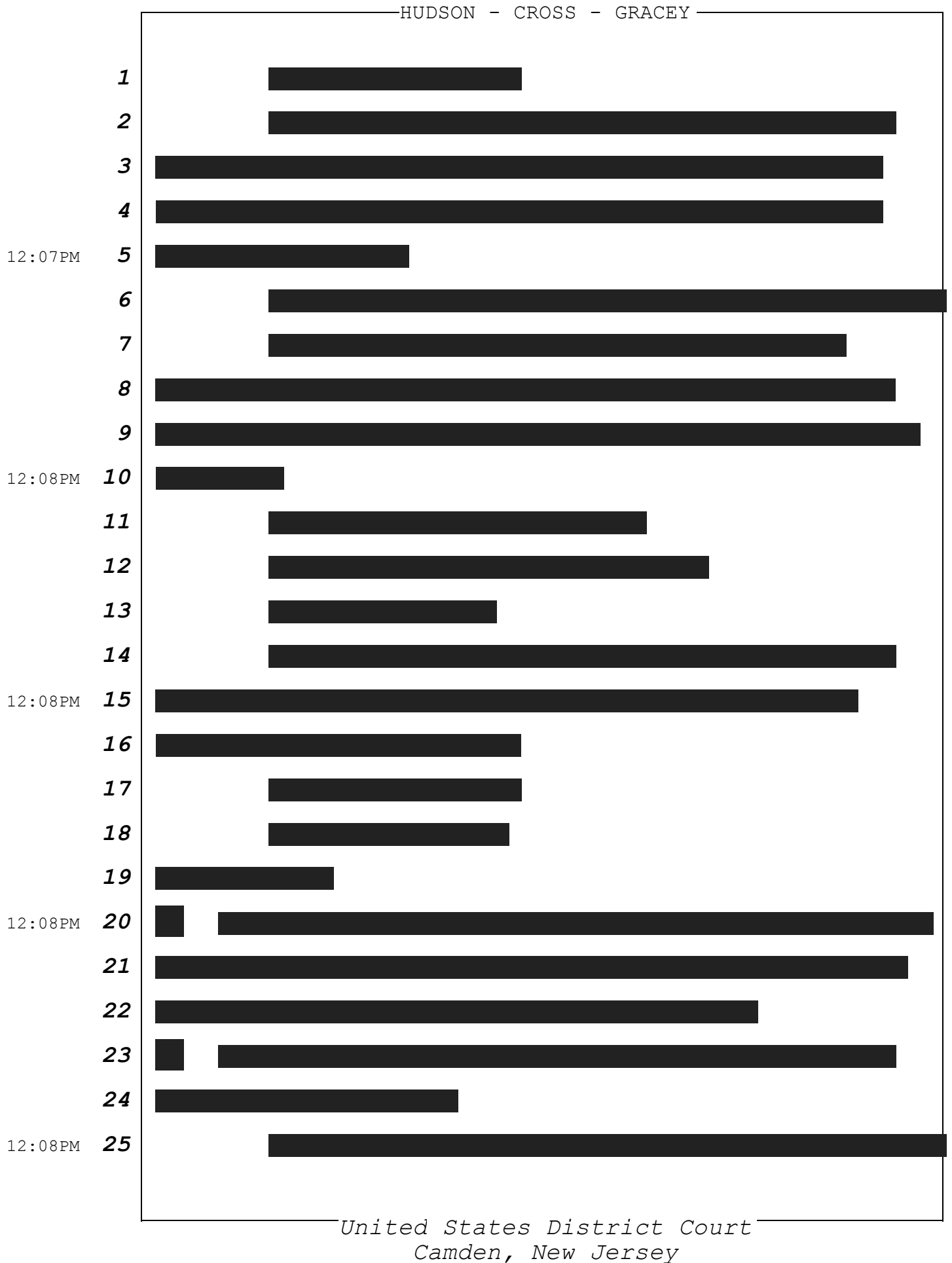
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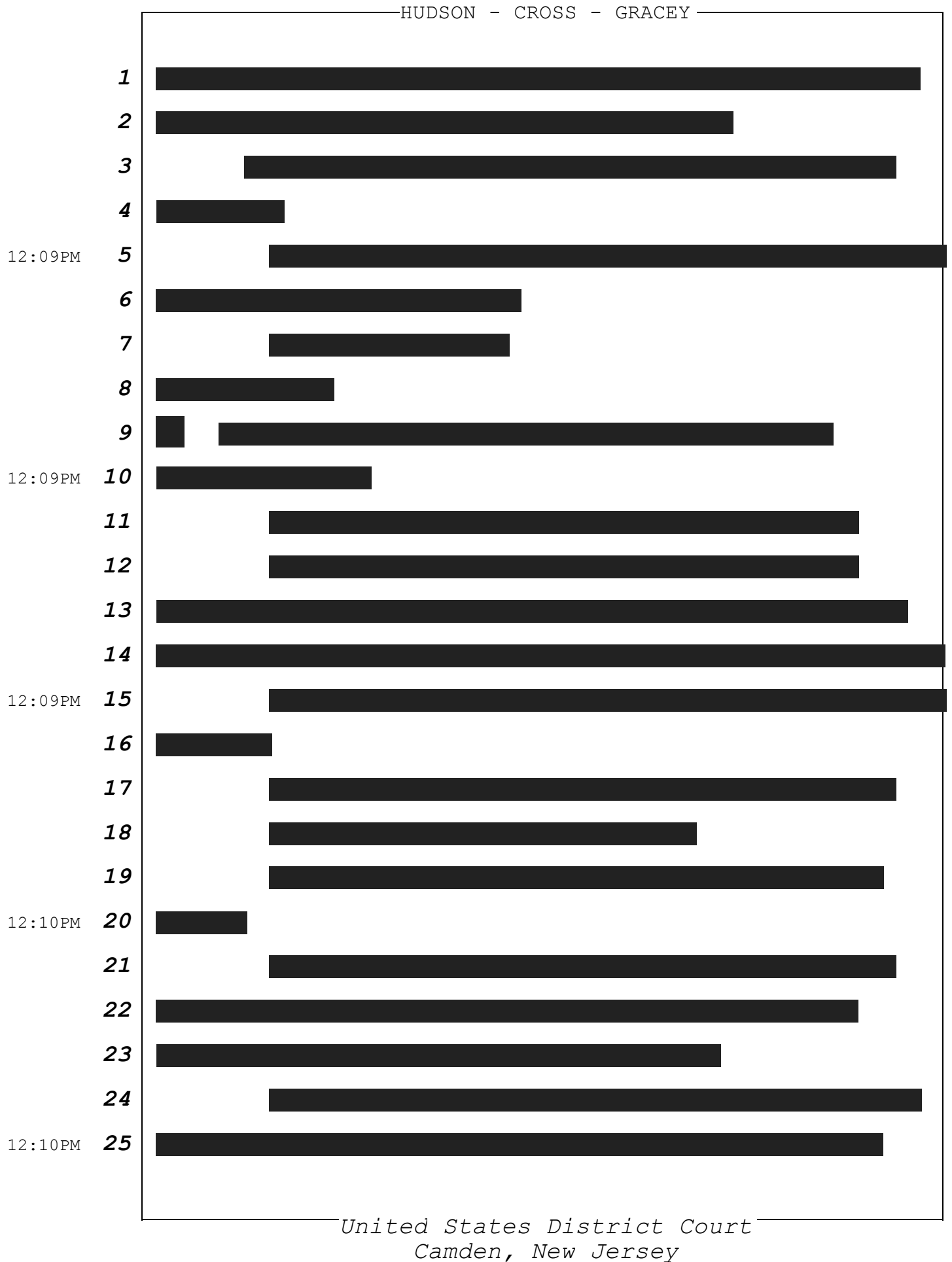
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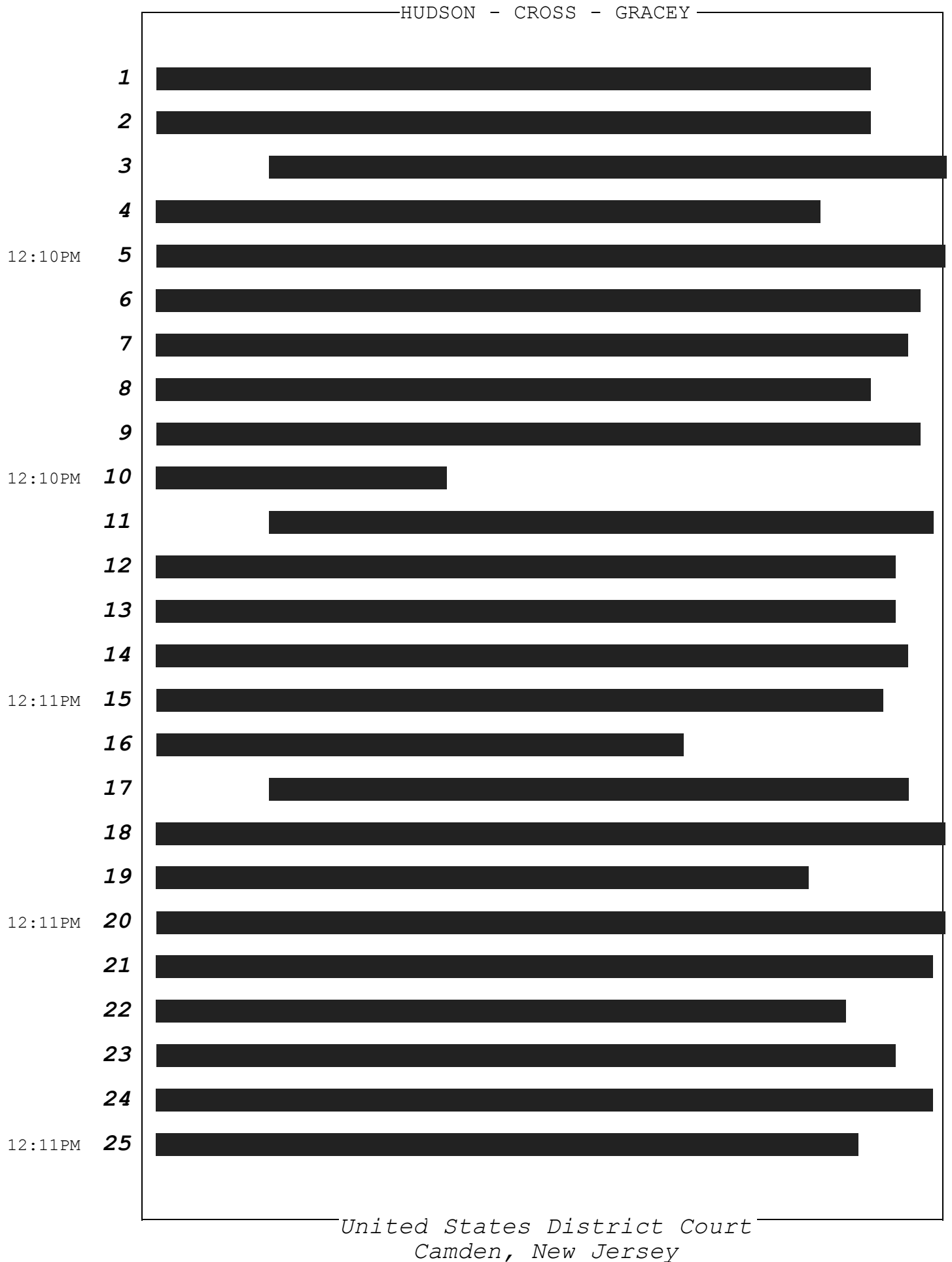


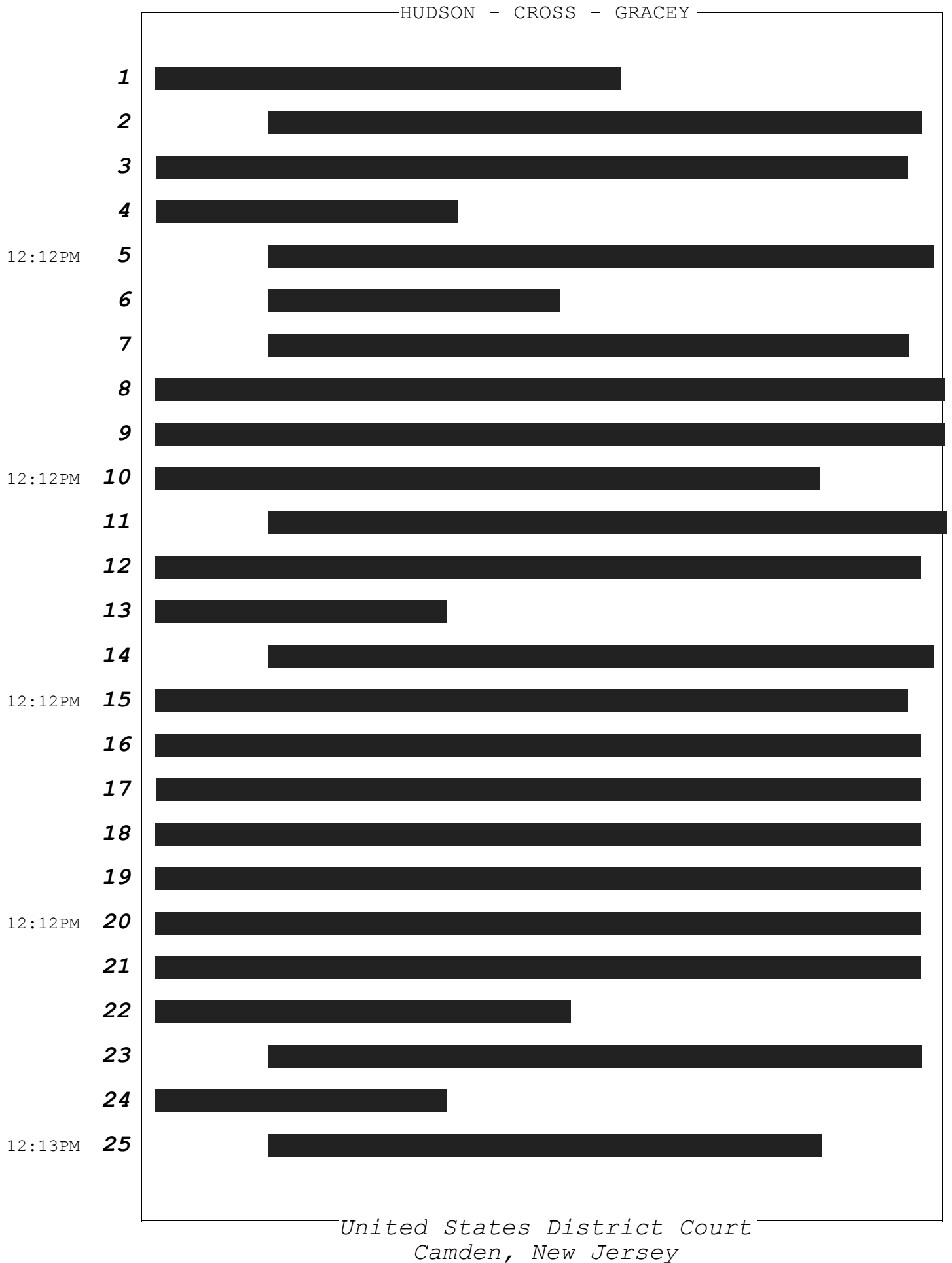


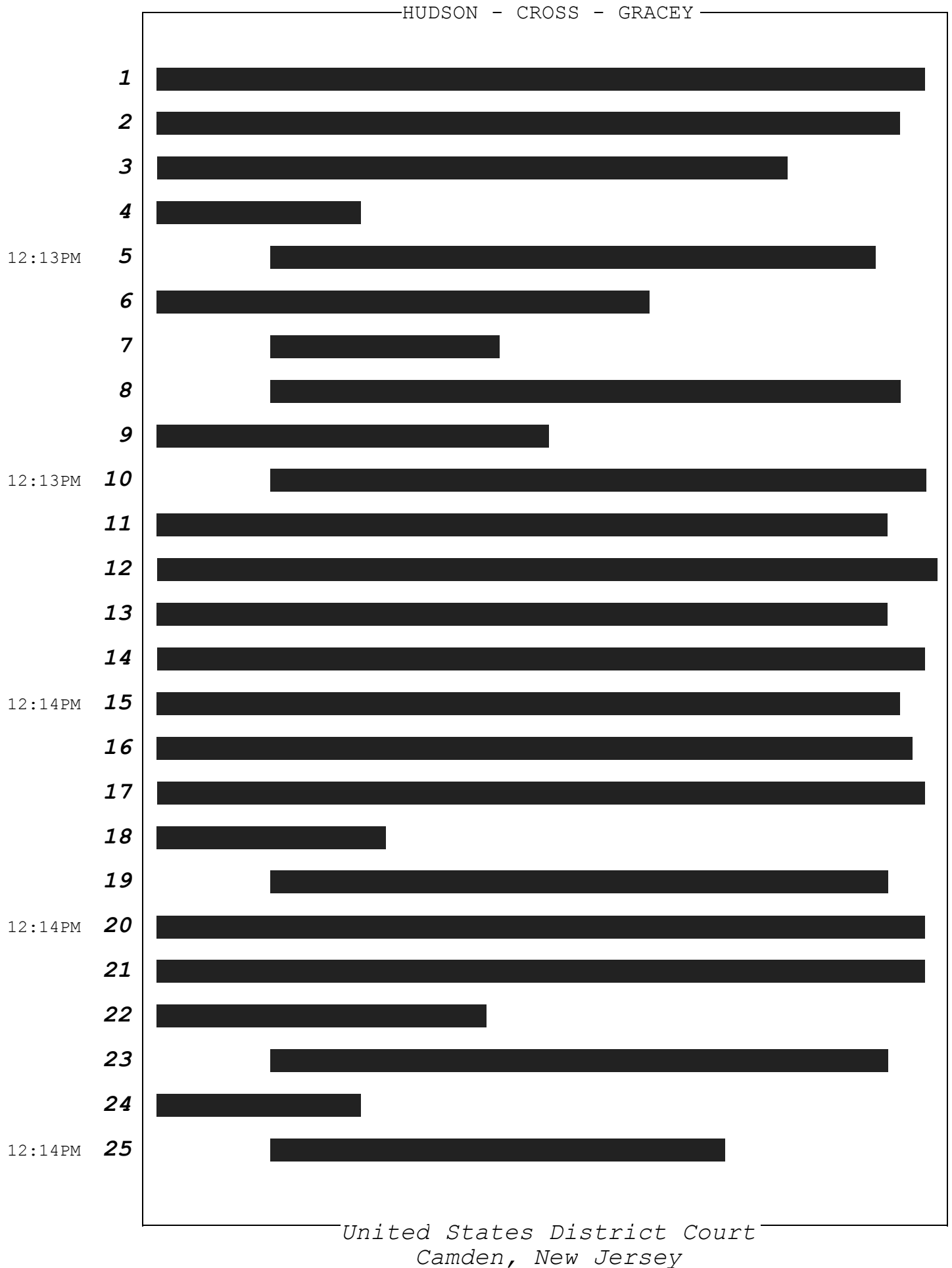


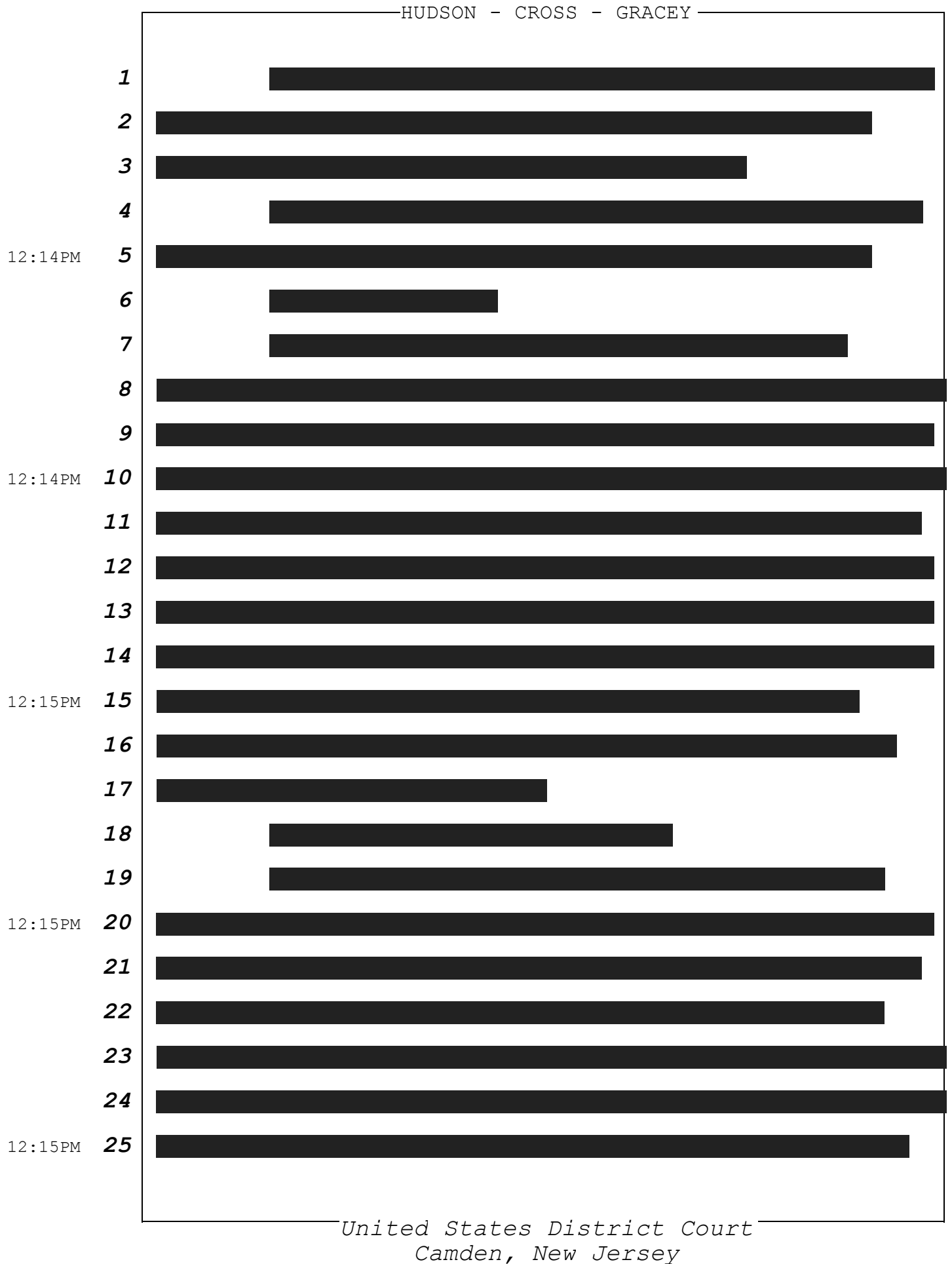


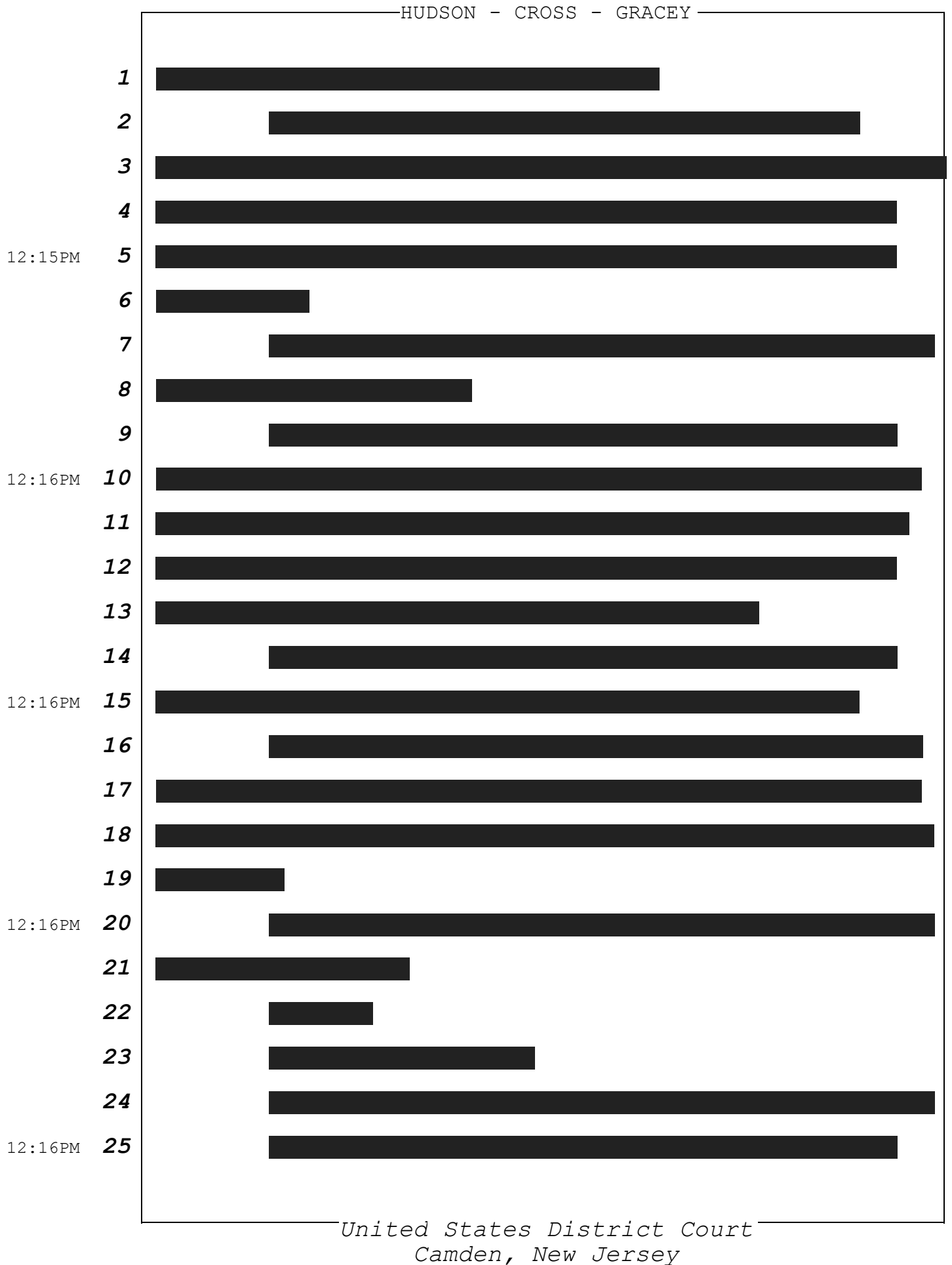


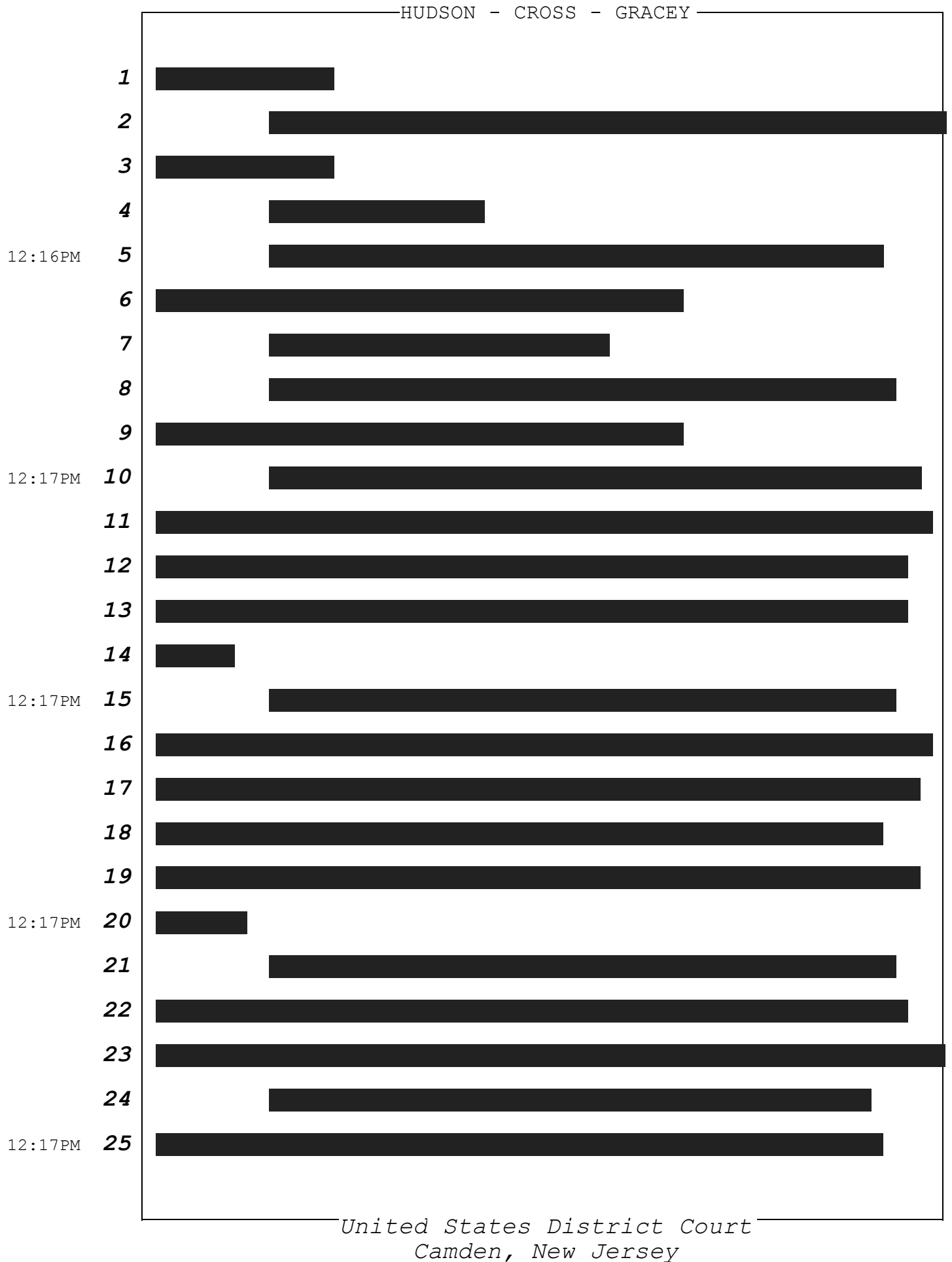


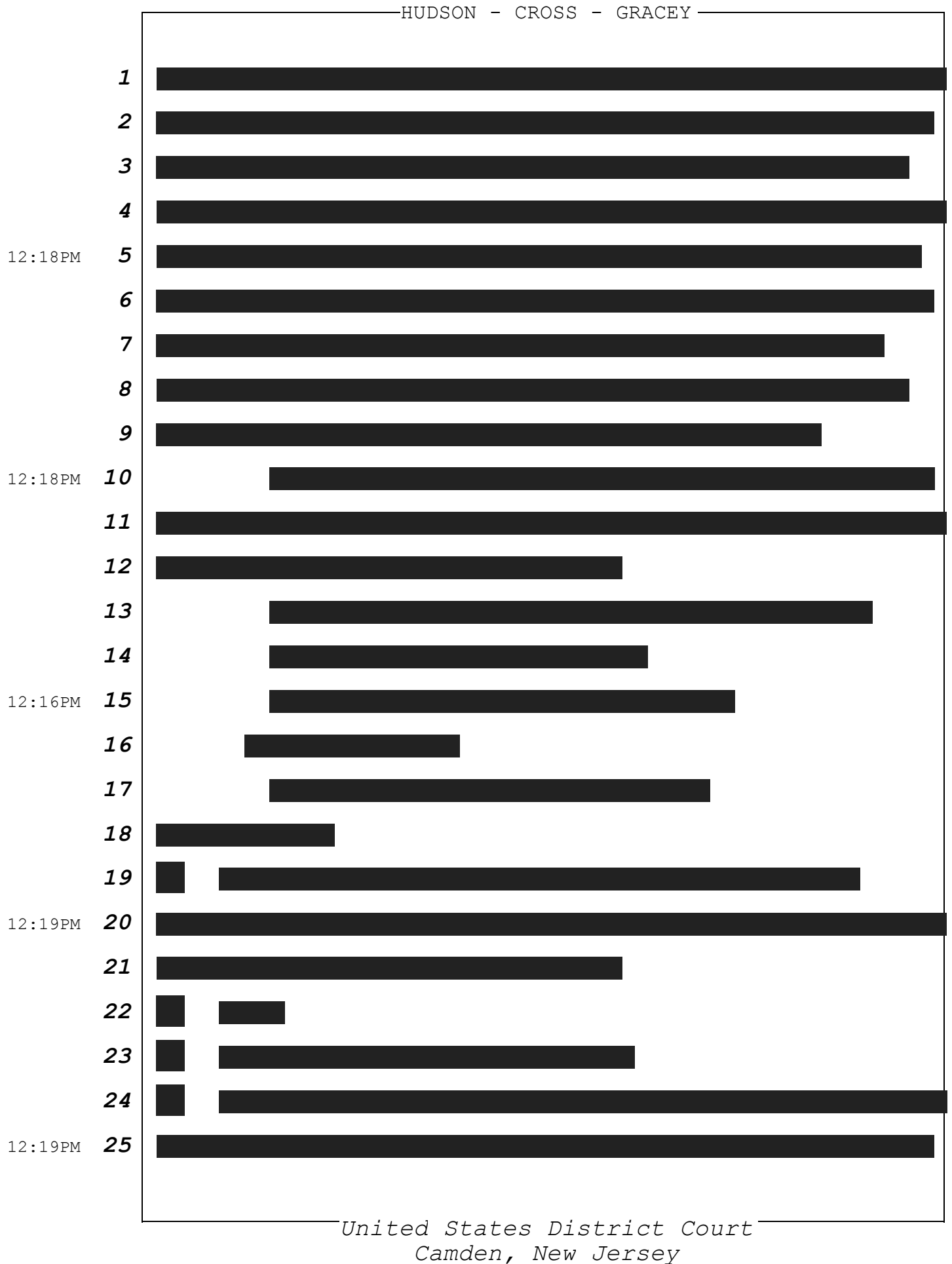


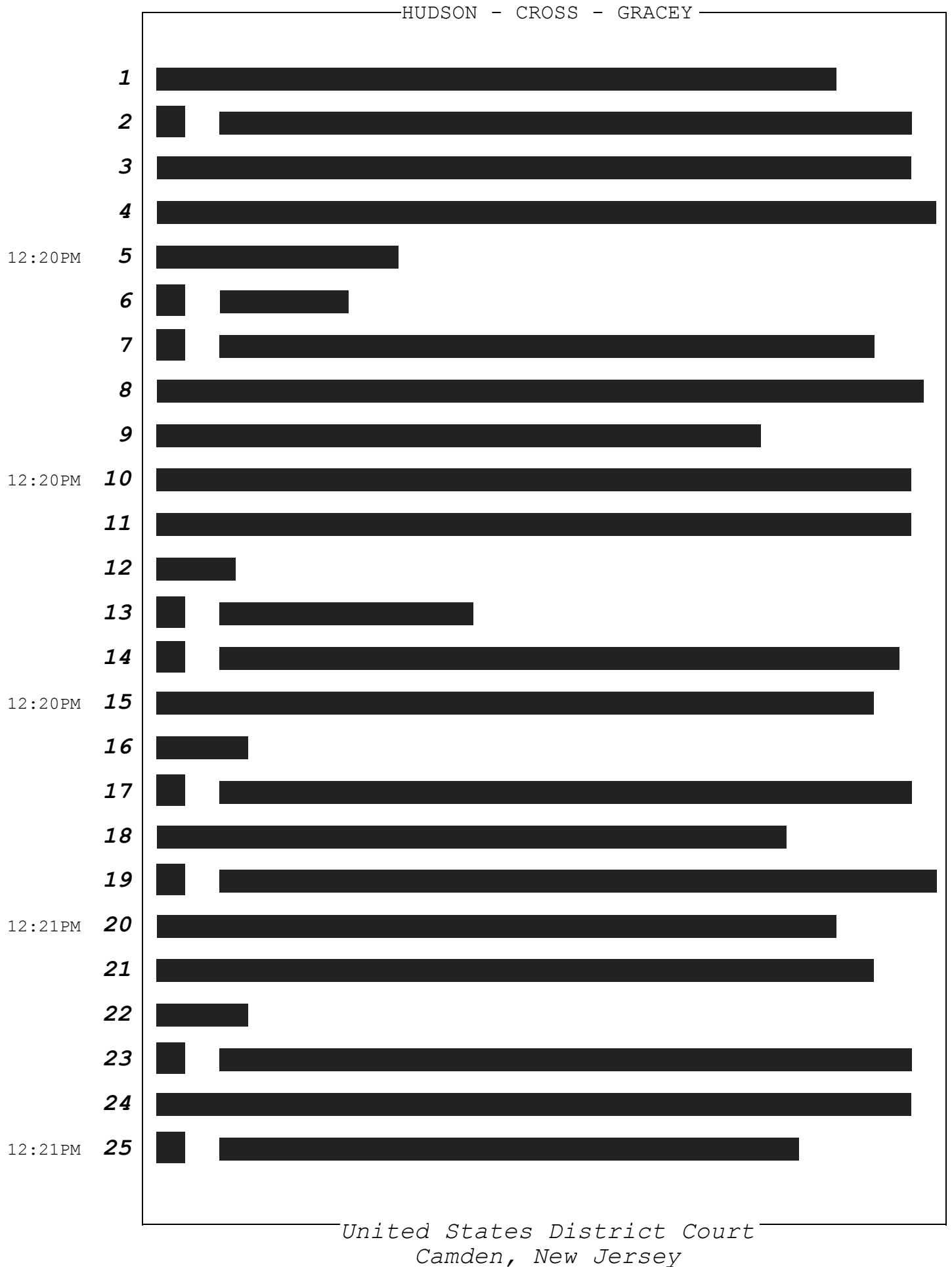


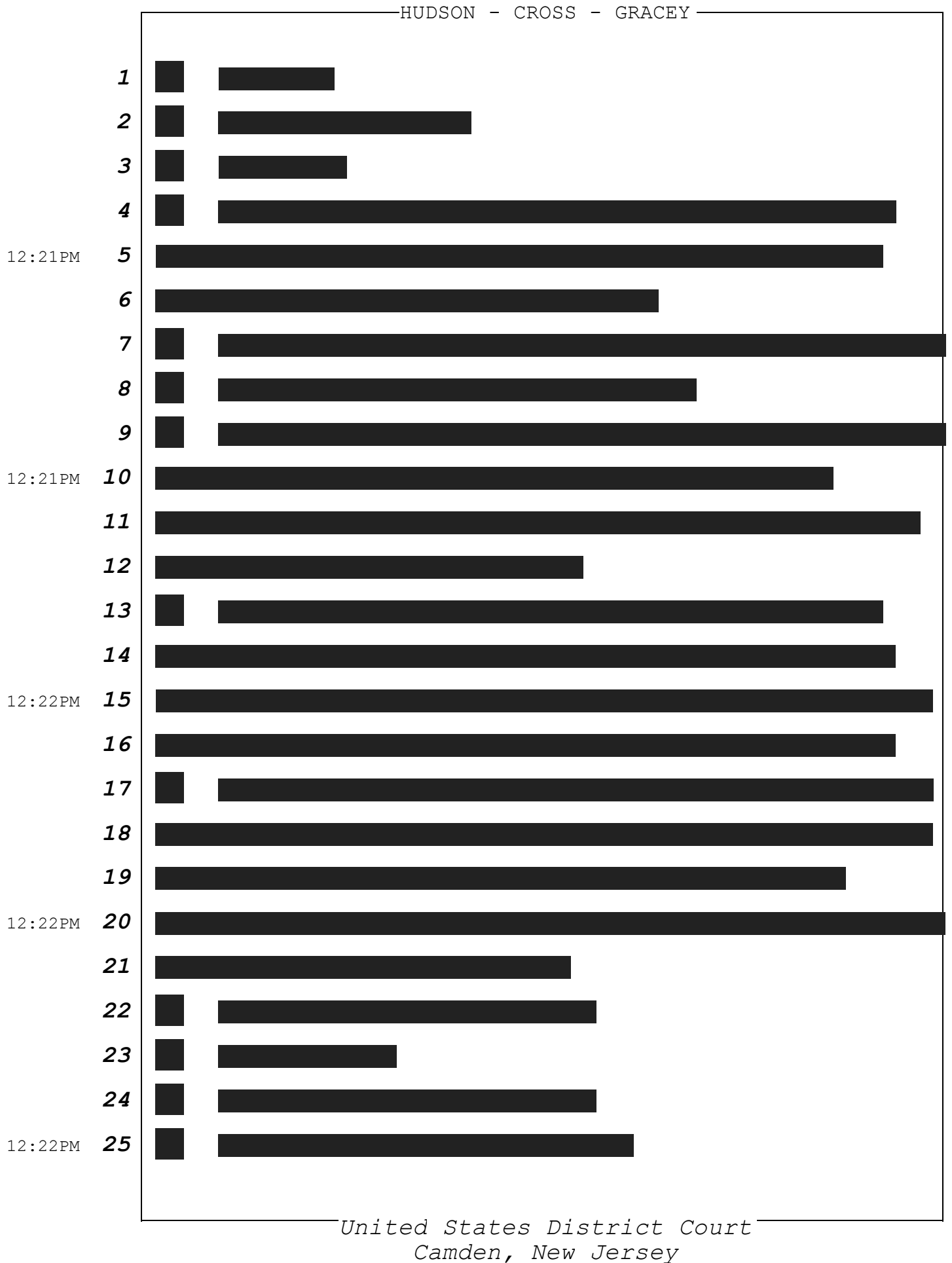






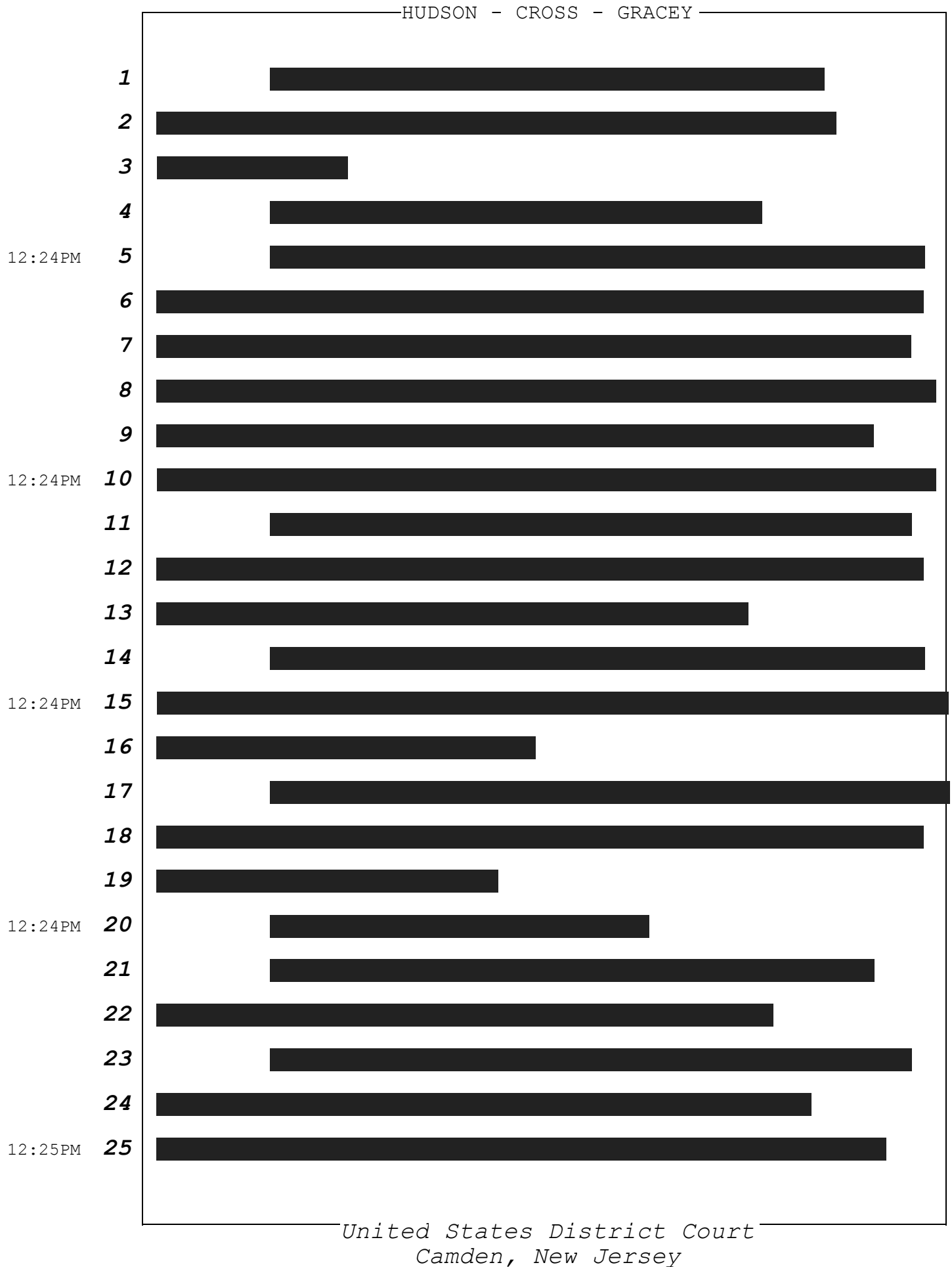


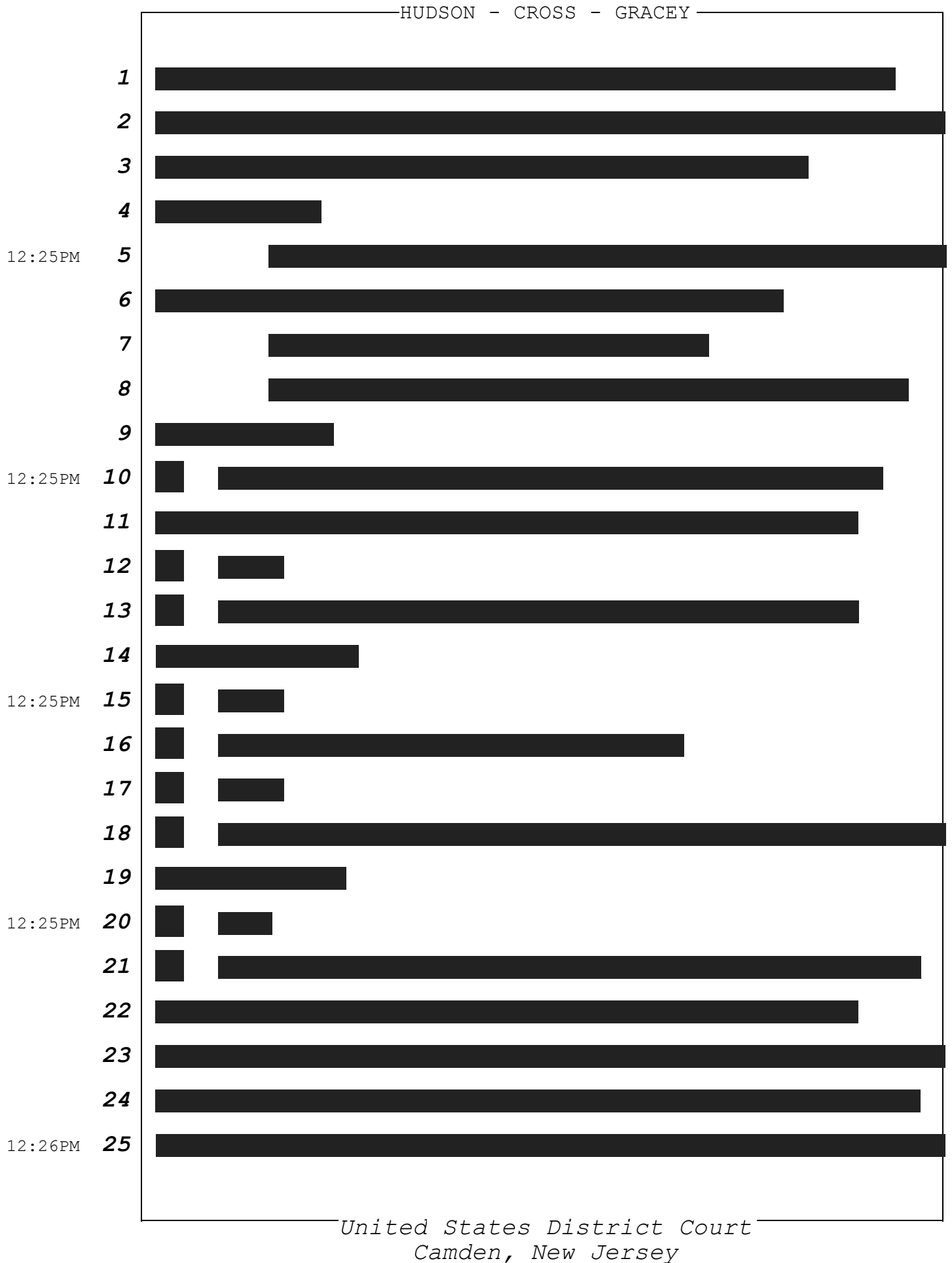


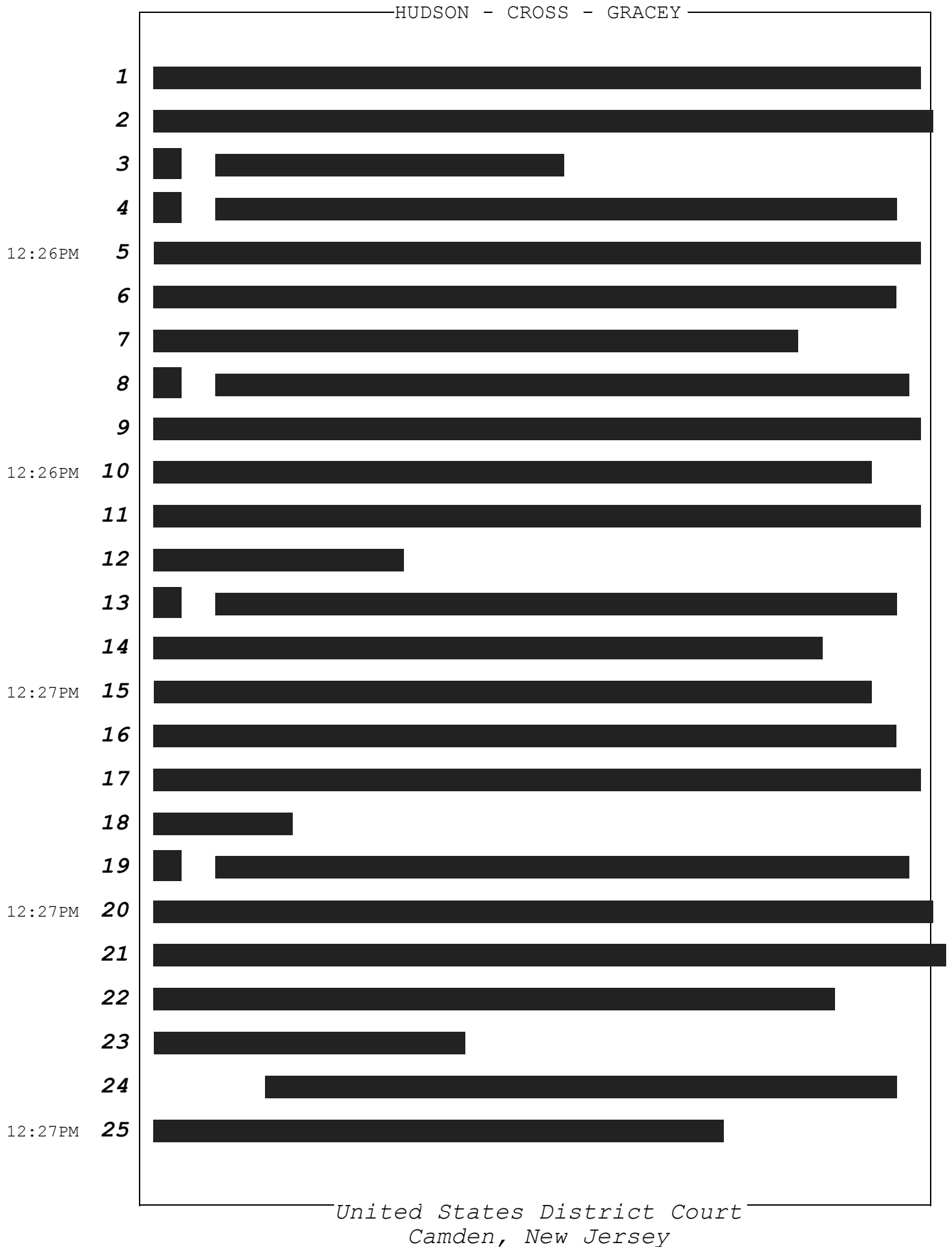


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—HUDSON - REDIRECT - ANTHONY—

1 (REDIRECT EXAMINATION OF MR. HUDSON BY MR. ANTHONY:)

2 Q. Mr. Hudson, you were asked a number of questions about
3 the royalty agreement with Teva. Do you remember?

4 A. Yes.

12:29PM 5 Q. Is Teva currently, including in the current year, paying
6 royalties to AstraZeneca under that agreement?

7 A. Yes.

8 Q. Is everything that you know consistent with the premise
9 that both of the parties to that agreement believe it to be
10 and are operating as it is still in force?

11 A. Absolutely.

12 MR. ANTHONY: I have no further questions of the
13 witness.

14 THE COURT: Okay. Anything on that question?

12:29PM 15 MS. BRODY: Nothing from Watson/Breath, your Honor.

16 MR. GRACEY: No.

17 THE COURT: Okay. Mr. Hudson.

18 THE WITNESS: Thank you.

19 THE COURT: Safe trip to London.

12:30PM 20 THE WITNESS: Thank you, your Honor.

21 (Witness excused.)

22 THE COURT: Good breaking spot. I was going to go a
23 little later since I kept you all waiting, but this is a good
24 breaking point?

12:30PM 25 MR. ANTHONY: Yes, your Honor.

HUDSON - REDIRECT - ANTHONY

1 THE COURT: All right. Have a good lunch. See you
2 in an hour.

3 THE DEPUTY COURT CLERK: All rise.

4 (Luncheon Recess at 12:30 p.m..)

01:39PM

5 (In open court at 1:39 p.m..)

6 THE DEPUTY COURT CLERK: All rise.

7 THE COURT: Okay. Be seated. Before you call your
8 next witness, I did have a -- I wanted to ask some questions
9 about the Teva agreement. So, I think the courtroom should be
10 sealed. If anyone is here who is not subject to the
11 confidentiality order, we'll have the courtroom sealed.

01:39PM

12 (By order of the Court, the courtroom was sealed.)

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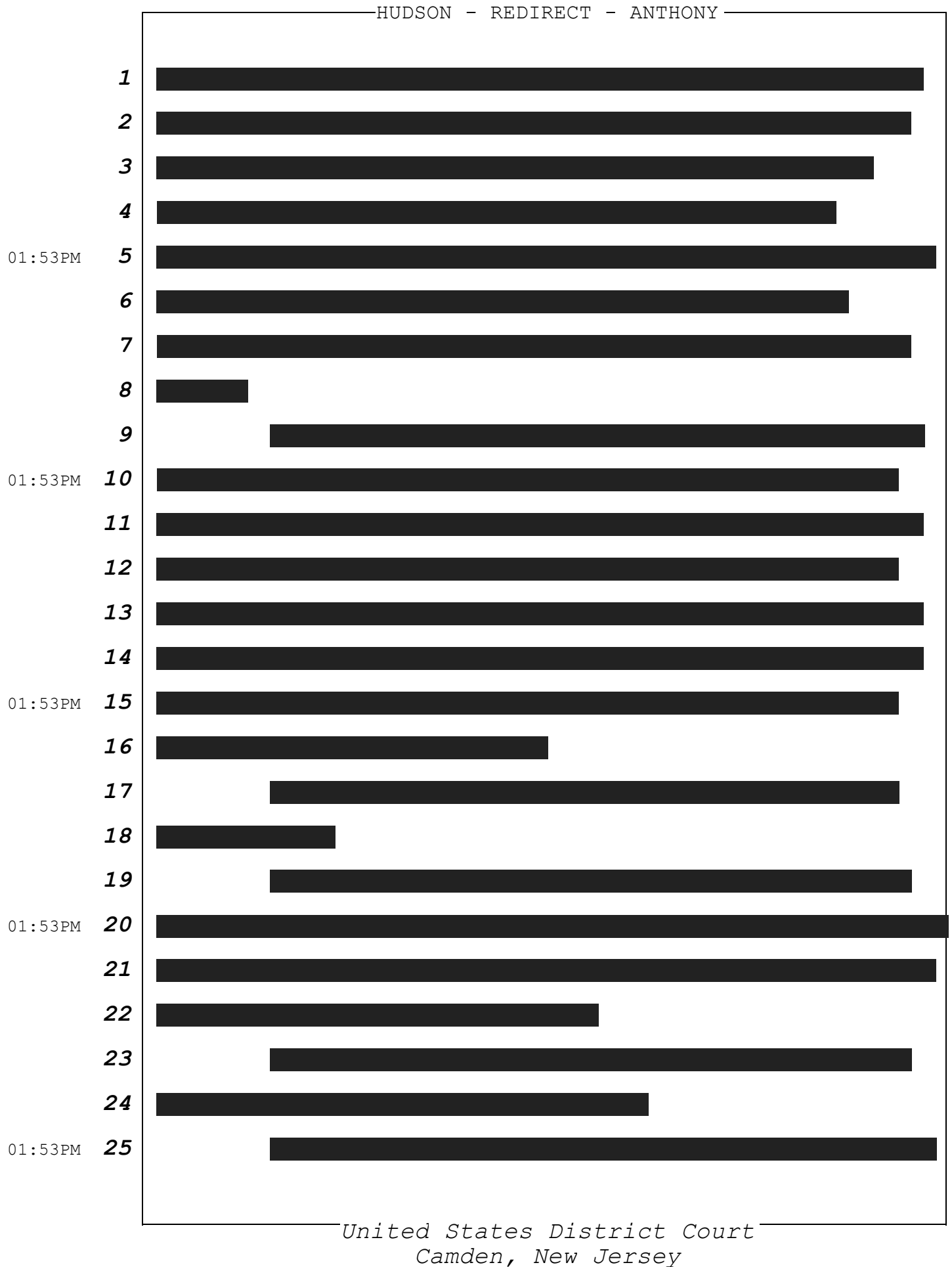
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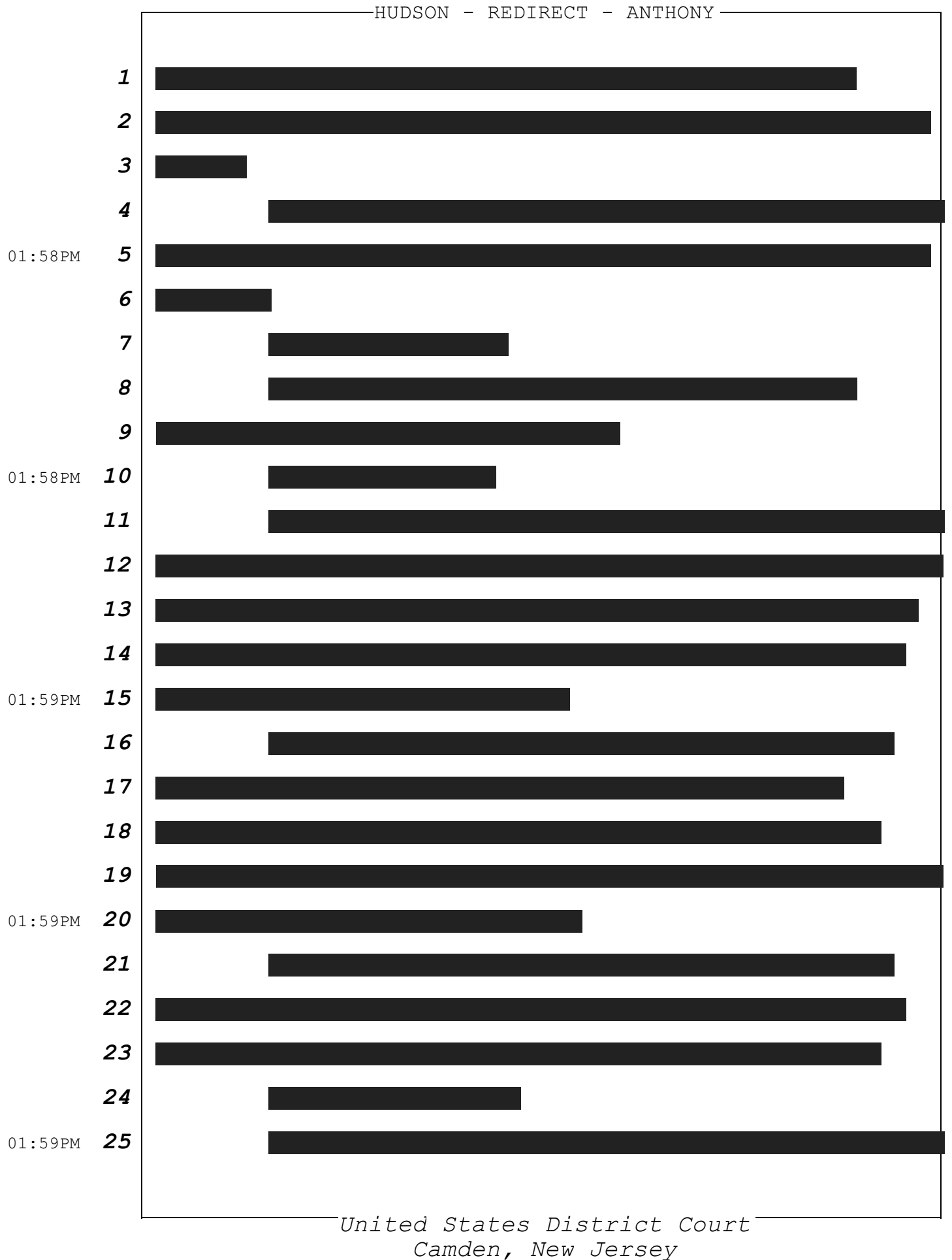
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	24	(By order of the Court, the courtroom was unsealed.)
02:01PM	25	THE COURT: And think about if this merits

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—Vellturo - Direct - Anthony—

02:01PM 1 additional, since you folks have probably already started
2 formulating your briefs and how much you wanted to devote to
3 each section, so think about if this would merit some
4 additional pages. I don't have any problem doing that. I'd
5 rather get it right.

6 MR. SIPES: Thank you, your Honor.

7 MR. ANTHONY: We will, your Honor. And just a
8 preview for the Court, the testimony we're about to put on is
9 going to address some of these issues.

02:01PM 10 THE COURT: Okay. Mr. Anthony, do you want to call
11 your witness?

12 MR. ANTHONY: Your Honor, AstraZeneca calls
13 Christopher Vellturo.

14 THE COURT: Okay.

02:02PM 15 THE DEPUTY CLERK: Good afternoon. Can you please
16 raise your right hand and put your left hand on the Bible..
17 **(DR. CHRISTOPHER ALAN VELLTURO, HAVING BEEN DULY SWORN AS A**
18 **WITNESS TESTIFIED AS FOLLOWS:)**

19 **(DIRECT EXAMINATION OF DR. VELLTURO BY MR. ANTHONY)**

02:02PM 20 THE DEPUTY CLERK: Can you please state and spell
21 your full name for the record.

22 THE WITNESS: Christopher Alan Vellturo,
23 V-E-L-L-T-U-R-O.

24 THE COURT: Okay. Nice to see you again.

02:02PM 25 THE WITNESS: Good afternoon.

—Vellturo - Direct - Anthony—

1 THE COURT: There is water there if you need it. And
2 please keep your voice up.

3 MR. ANTHONY: Your Honor, we have direct examination
4 binders for the witness and for the court and for counsel.

02:02PM 5 THE COURT: Okay. Thank you.

6 MR. ANTHONY: If we can take a moment to distribute
7 those.

8 (Short pause.)

9 BY MR. ANTHONY:

02:03PM 10 Q. Do you have the binder in front of you, Dr. Vellturo?

11 A. I do.

12 Q. Okay, great. Thank you. Dr. Vellturo, you previously
13 testified before this court earlier in this very trial, did
14 you not?

02:03PM 15 A. Yes.

16 Q. Did you prepare a set of demonstrative slides to help you
17 present your testimony to the court to today?

18 A. I did.

02:03PM 19 Q. And is this PDX-28.1 that we have on the screen, is that
20 your demonstratives?

21 A. This is the first of the slides, yes.

22 Q. Let's turn to Slide 2, if we may. This may have a
23 familiar look to it, Dr. Vellturo. Is this a summary of your
24 qualifications?

02:03PM 25 A. It is.

—Vellturo - Direct - Anthony—

1 Q. Okay. Other than adding a reference to the point in the
2 2014 trial transcript where you were previously qualified, is
3 this a similar summary to the one you presented to the court
4 in your previous testimony in this trial?

02:04PM

5 A. Yes.

6 Q. Have there been any significant changes in your
7 qualifications since the last time you provided testimony to
8 the court?

9 A. No.

02:04PM

10 Q. What subjects, Dr. Vellturo, are you present in court to
11 testify about today?

12 A. I am here to testify about irreparable harm matters.

13 Q. Okay.

14 MR. ANTHONY: And, your Honor, we offer Christopher

02:04PM

15 Vellturo as an expert in the field of economics, including
16 specifically the economics of the pharmaceutical industry,
17 econometrics and statistical principles. Those with the
18 topics on which he was previously qualified.

19 THE COURT: Okay. There is no objection?

02:04PM

20 MR. GRACEY: No objection from Sandoz.

21 MR. RAKOCZY: No objection, your Honor.

22 MR. BASILE: No objection, your Honor.

23 THE COURT: Pursuant to Rule 702, he'll be permitted
24 to continue his testimony as an expert.

02:04PM

25 MR. ANTHONY: Thank you.

—Vellturo - Direct - Anthony—

1 BY MR. ANTHONY:

2 Q. Dr. Vellturo, could you summarize for the court the way
3 you went about your analysis as it relates to the issue of
4 irreparable harm in this case?

02:05PM **5** A. Yes. So I undertook an analysis to understand the likely
6 economic impacts that would be associated with certain
7 scenarios under which injunctions are or are not issued, and I
8 identified the nature of the financial and non financial harms
9 that would inure to AstraZeneca as a result.

02:05PM **10** Q. Did you review certain financial information and sales
11 information that you've received from the company in
12 connection with your work?

13 A. I did.

14 Q. Could we put before the witness, and I ask you to turn in
02:05PM **15** your binder to DTX-2044 in evidence. We saw this earlier
16 today, Dr. Vellturo. What is DTX-2044?

17 A. DTX-2044 is a table that has various financial
18 information from AstraZeneca as to U.S. sales and other
19 statistics relating to Pulmicort Respules.

02:06PM **20** Q. Were you present in the courtroom today for the testimony
21 of Paul Hudson about this?

22 A. Yes, I was.

23 Q. Now, if we could put up, Mr. Beall, PTX-1973. And if I
24 could ask you to turn to in your binder, Dr. Vellturo,

02:06PM **25** PTX-1973. What is that?

—Vellturo - Direct - Anthony—

1 A. PTX-1973 would be an exhibit I prepared as part of one of
2 my declarations in this matter.

3 Q. Okay. And what source did you base PTX-1973 on?

02:06PM

4 A. Well, PTX-1973 is not only based off of DTX-2044, it's
5 actually the same numbers. This is just a reformatting of the
6 same data.

7 Q. Okay. So among other things, did you determine the total
8 sales in dollars of net sales of Pulmicort Respules from
9 September 2000 to May 2014?

02:07PM

10 A. I did.

11 Q. And what was of the total amount?

12 A. \$5,636,000,000.

02:07PM

13 Q. And in the course of your work looking at irreparable
14 harm in this case, did you conduct an analysis of the likely
15 affect on AstraZeneca of a launch of unlicensed BIS or
16 budesonide inhalation suspension by the three defendants in
17 this case?

18 A. Yes, I did.

02:07PM

19 Q. In your analysis did you consider the history of BIS
20 sales in the United States?

21 A. Yes.

22 Q. Okay. If we could go back to the demonstrative and turn
23 to Slide 3. So we're looking at PDX-28.3. Is this a blown-up
24 portion of PTX-1973 with some notations on it?

02:07PM

25 A. It is a blowup of a portion of PTX-1973, and I added a

—Vellituro - Direct - Anthony—

1 couple of percentage decline numbers to the chart.

2 Q. What analysis did you conduct with regard to sales of
3 branded Pulmicort Respules from 2008 to 2013? What you have
4 blown-up on the screen?

02:08PM 5 A. Well, the last time I was here I testified about a fact
6 that as of 2008 Pulmicort Respules as a branded drug in the
7 United States was heading towards blockbuster status. I
8 believe I testified they were approaching 900 million in
9 sales. That number actually appears here under 2008 as
02:08PM 10 \$874 million.

11 What this chart then goes onto show is the subsequent
12 impact on branded Pulmicort Respules of the continued sale
13 under license of the Teva generic in the United States.

14 Q. And what do the red arrows and percentages represent?

02:08PM 15 A. Those are the percentage declines on a calendar year
16 basis between 2008 and 2013. So net sales in dollars declined
17 by 85.6 percent and sales of units in numbers of 30 packages,
18 although the percentage would be the same no matter how you
19 did it, is an 86.8 percent decline.

02:09PM 20 Q. And you mentioned Teva, which I think -- let me turn to
21 my next question. What event occurred between 2008 and 2013
22 in relation to this declines? What did it represent?

23 A. This would be the time period under which Teva had made
24 available for sale generic BIS product in the United States.

02:09PM 25 Q. And did you consider those declines in the context of

—Vellturo - Direct - Anthony—

1 analyzing the effect of launches of unlicensed BIS by the
2 three defendants in this case?

3 A. Yes.

4 Q. How did the post 2008 experience of branded Pulmicort
5 factor into your analysis?

6 A. In two primary ways. First of all, it provided me, let's
7 say, confirmation of something that I've observed many, many
8 times and that I think is fairly commonly observed, is, for
9 reasons I'm going to talk about a little bit in terms of the
10 nature of the structure of the pharmaceutical industry,
11 generic introduction essentially eviscerates branded sales
12 pretty much no matter what the branded company tries to do.
13 And I'll explain that in a bit. That's the first point.

14 And then the second point is this provided me the
15 context under which I then needed to go forward and evaluate
16 what unauthorized generic launch would mean that I needed to
17 consider both Pulmicort Respules as a branded product and
18 Teva's generic as well.

19 Q. My next question is a yes or no for now. In considering
20 the effect of launches of unlicensed BIS by the three
21 defendants in this case, did you consider the effect of such
22 event on the royalties paid by Teva?

23 A. Yes, I did.

24 MR. ANTHONY: At this time I would ask that we seal
25 the courtroom because there is a considerable extent of

—Vellturo - Direct - Anthony—

1 discussion that would go into the royalty rates.

2 THE COURT: Except for Mr. Levy?

3 MR. ANTHONY: Again, except for Mr. Levy, yes.

4 THE COURT: So the courtroom is sealed to the public.

02:11PM 5 So if we can seal the courtroom, please.

6 (By order of the court, the courtroom was sealed.)

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

02:11PM 10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

02:11PM 15 [REDACTED]

16 [REDACTED]

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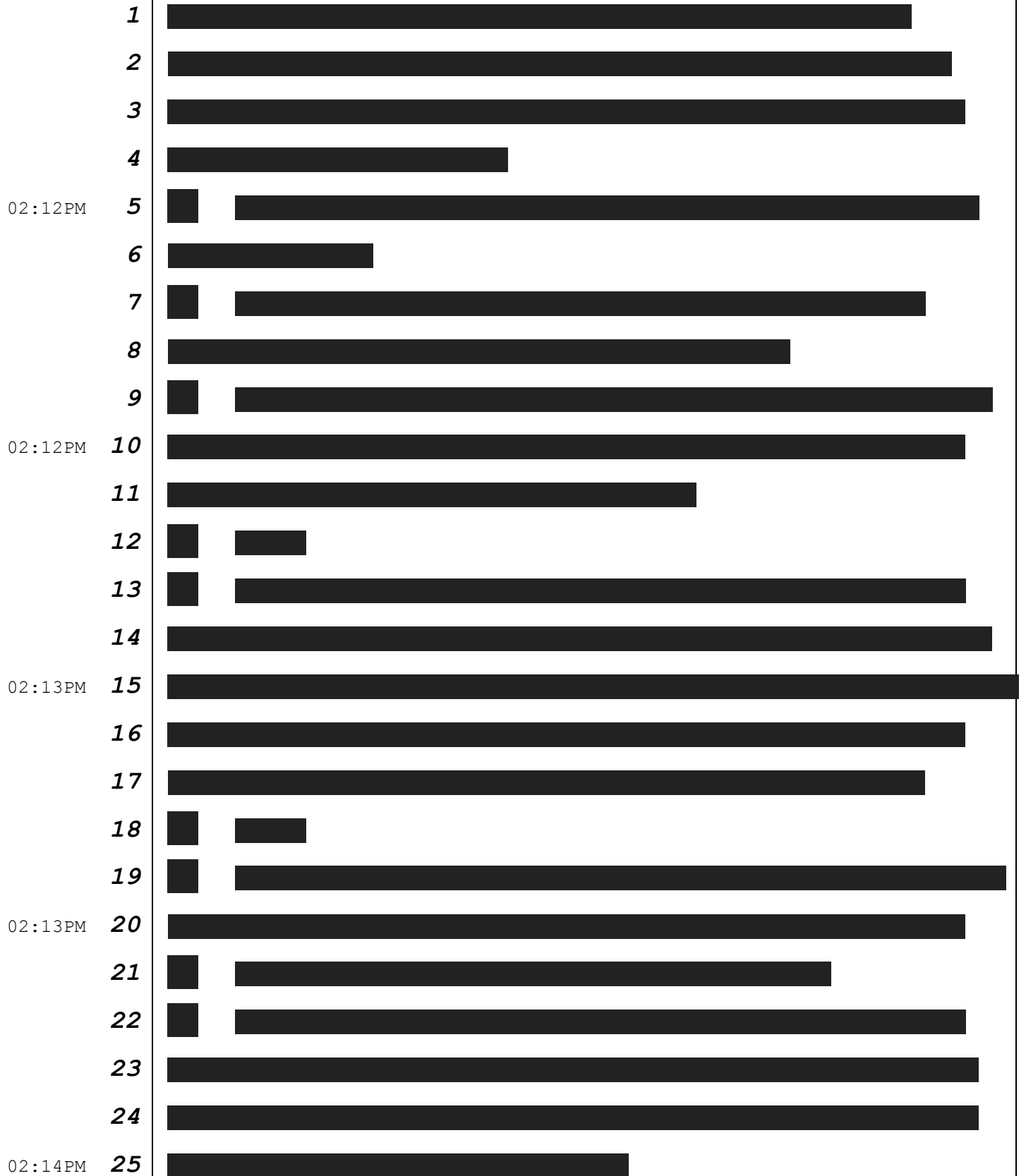
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24 [REDACTED]

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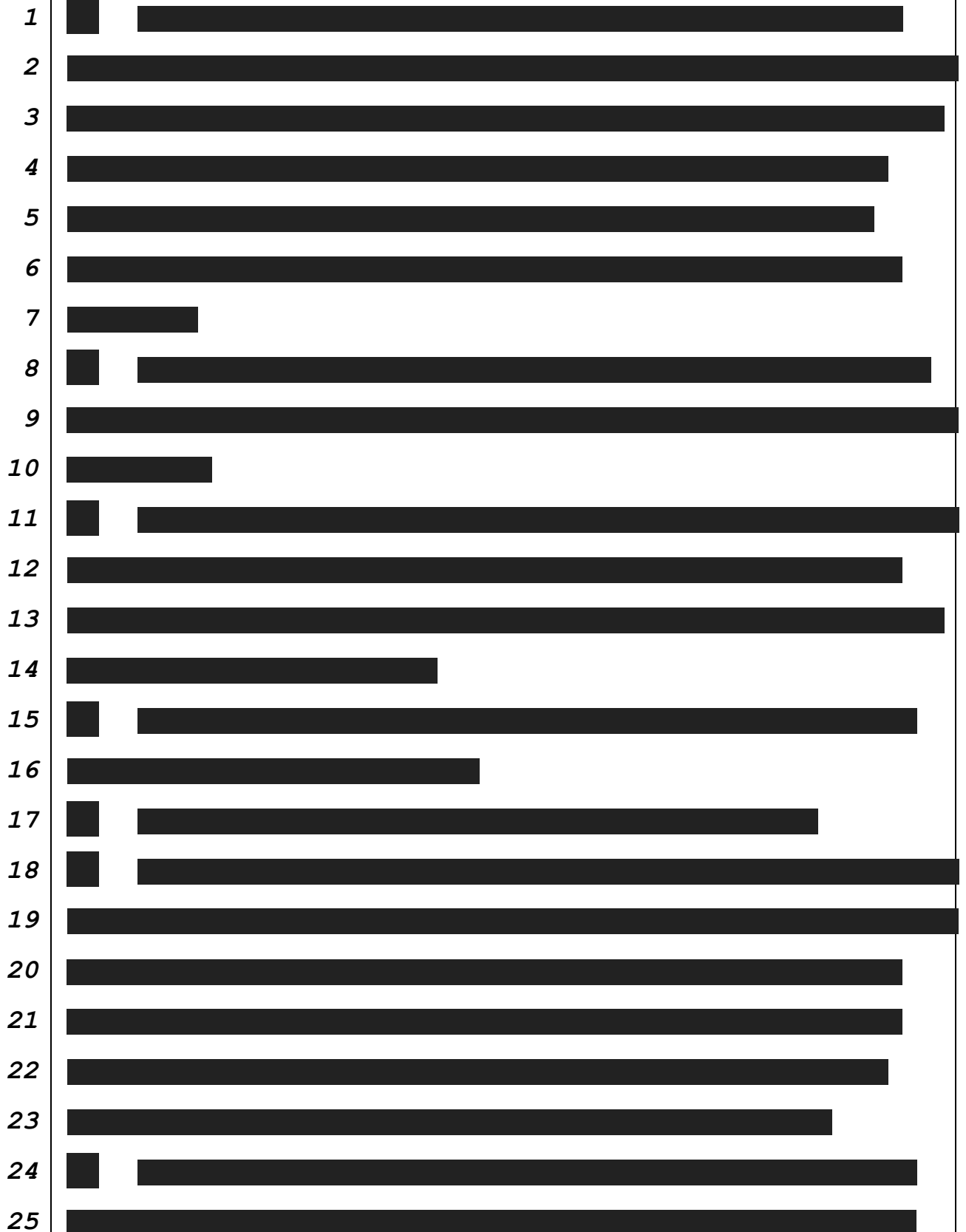
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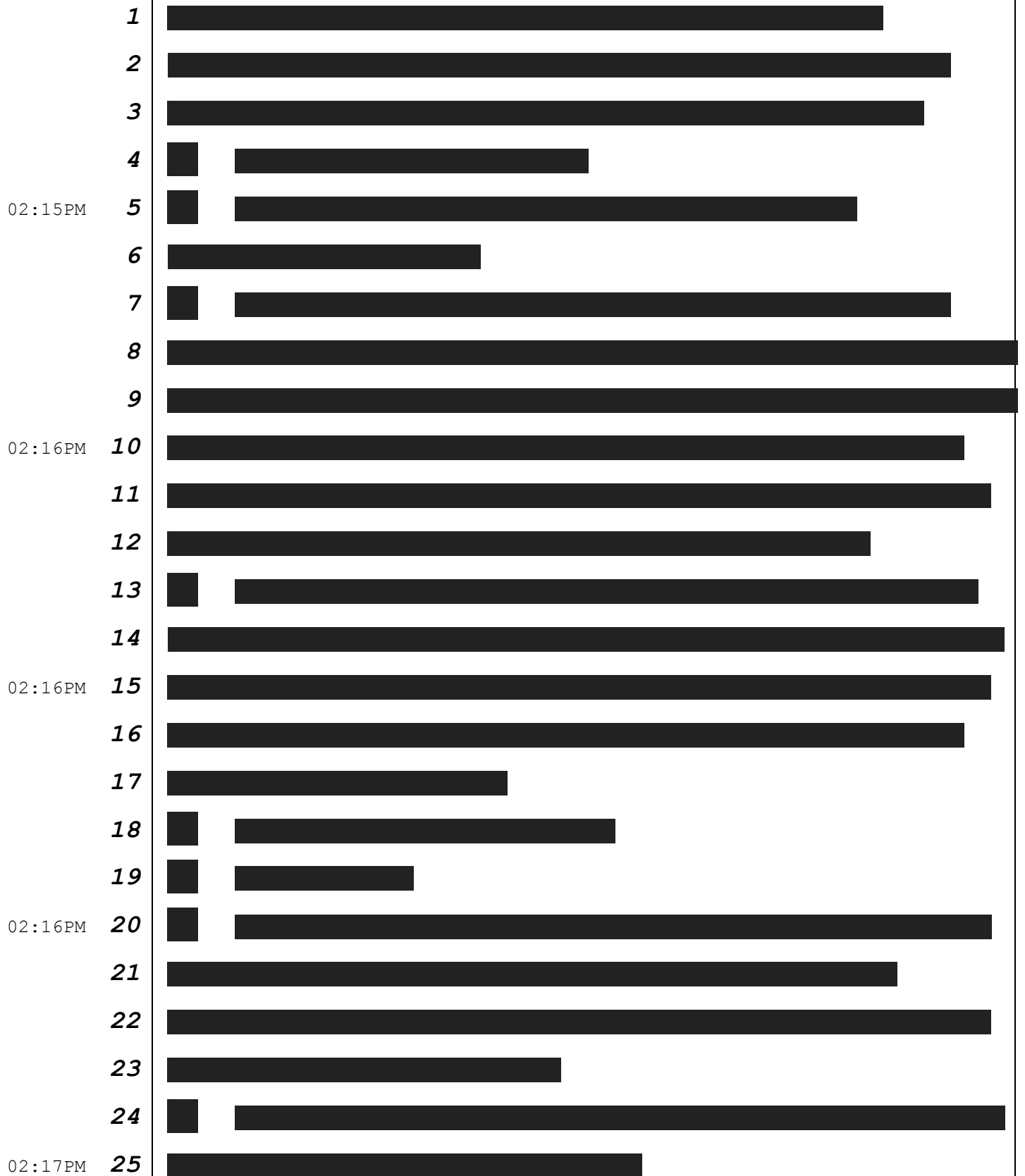
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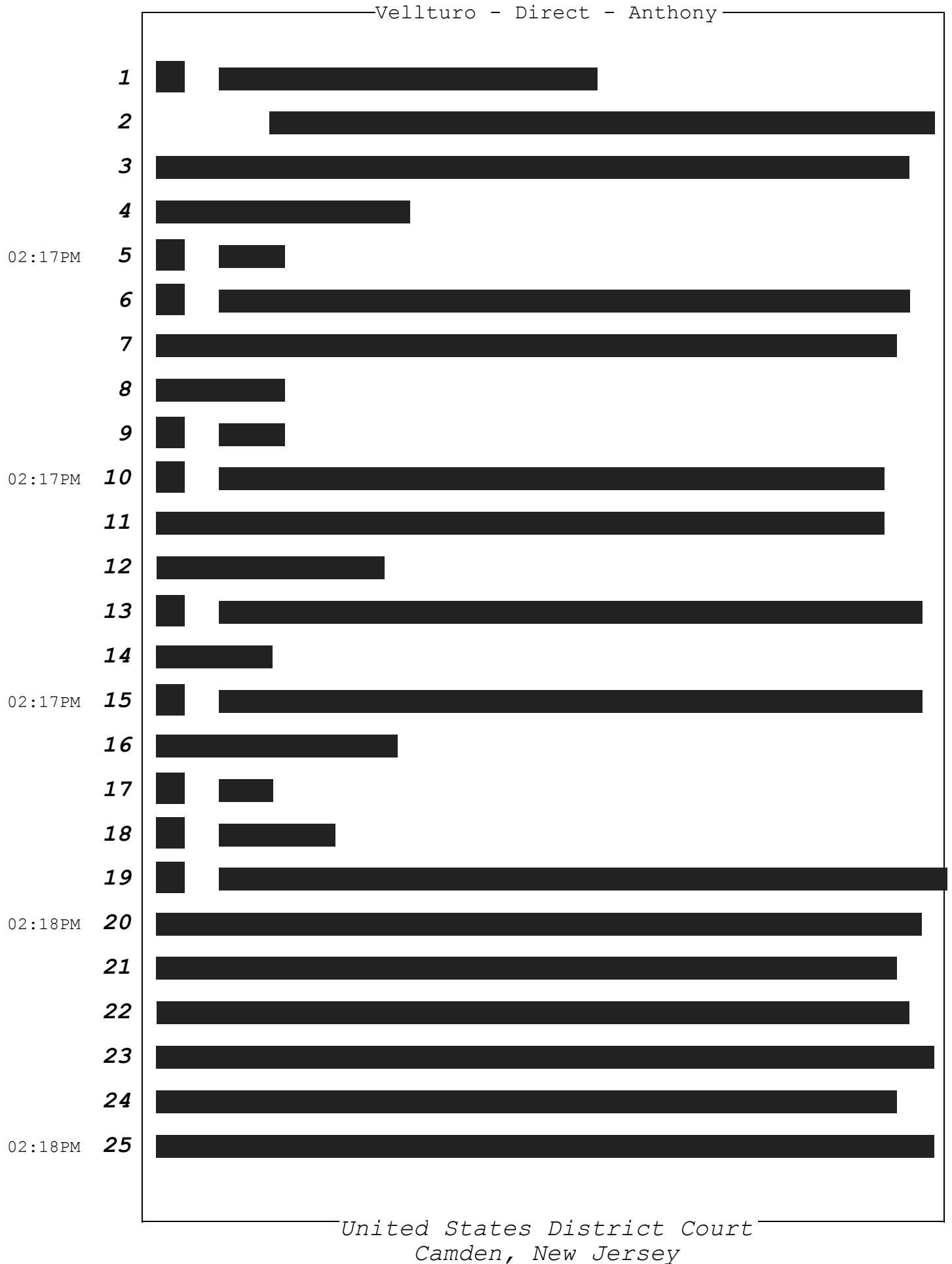


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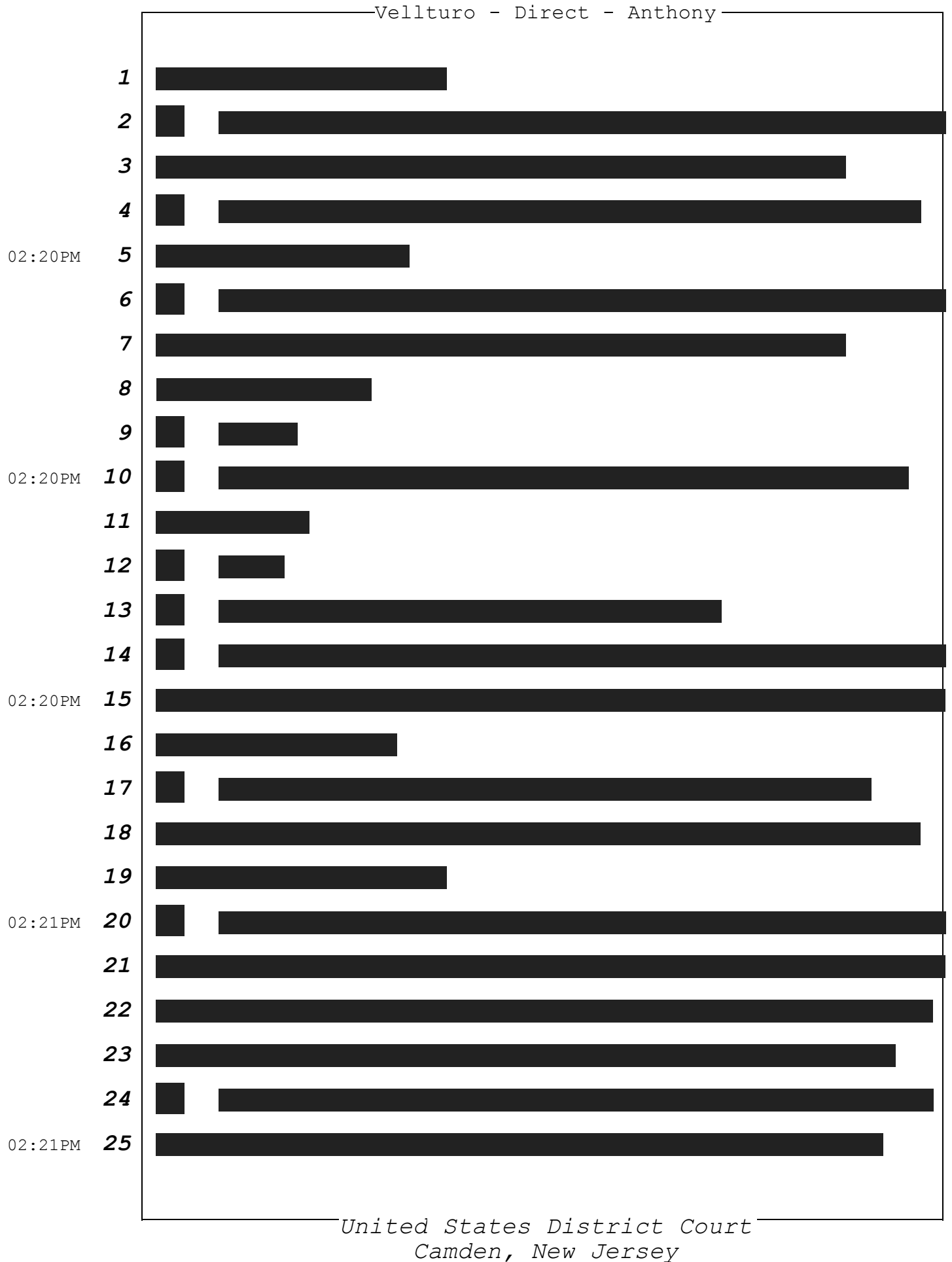
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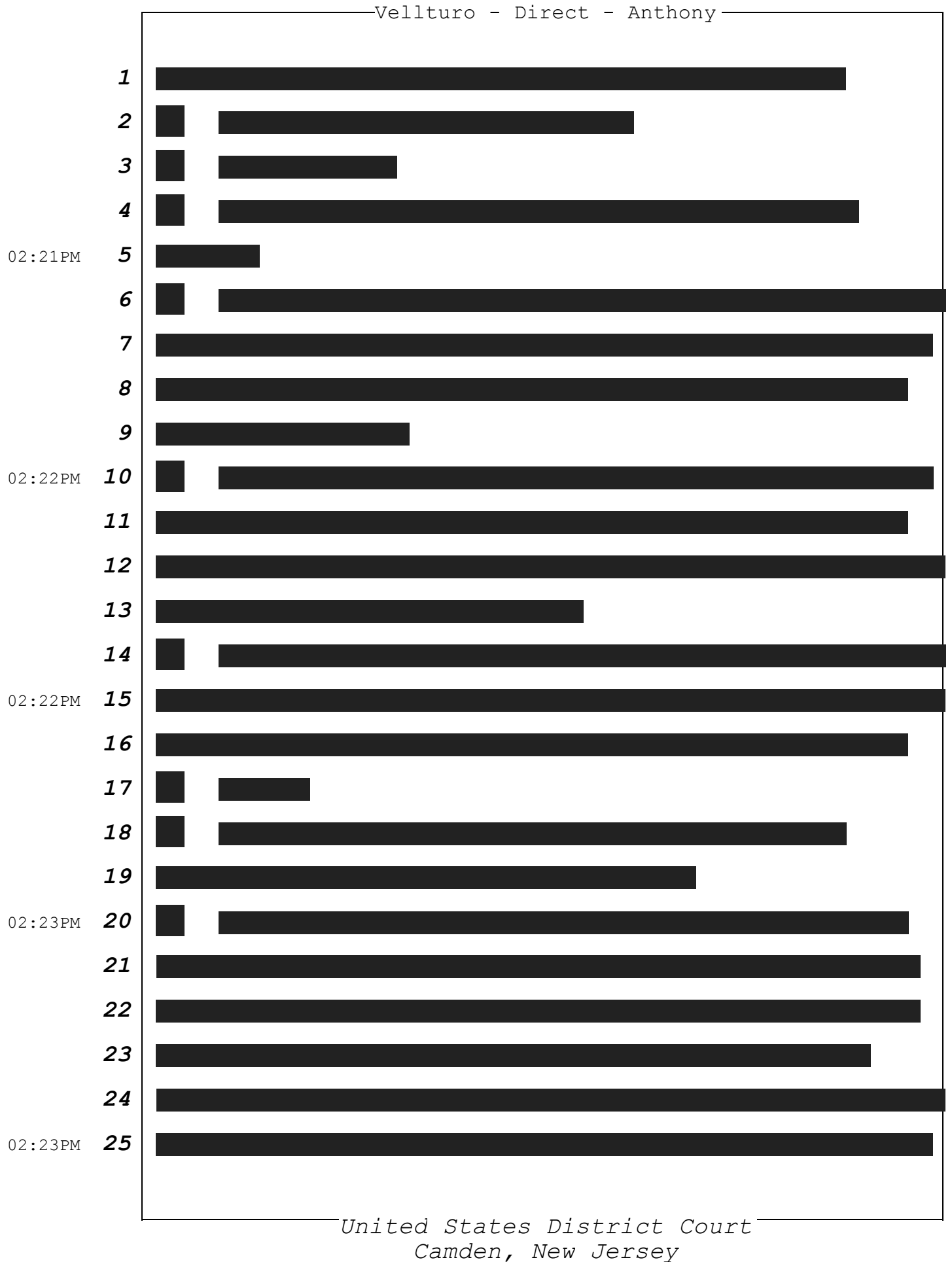


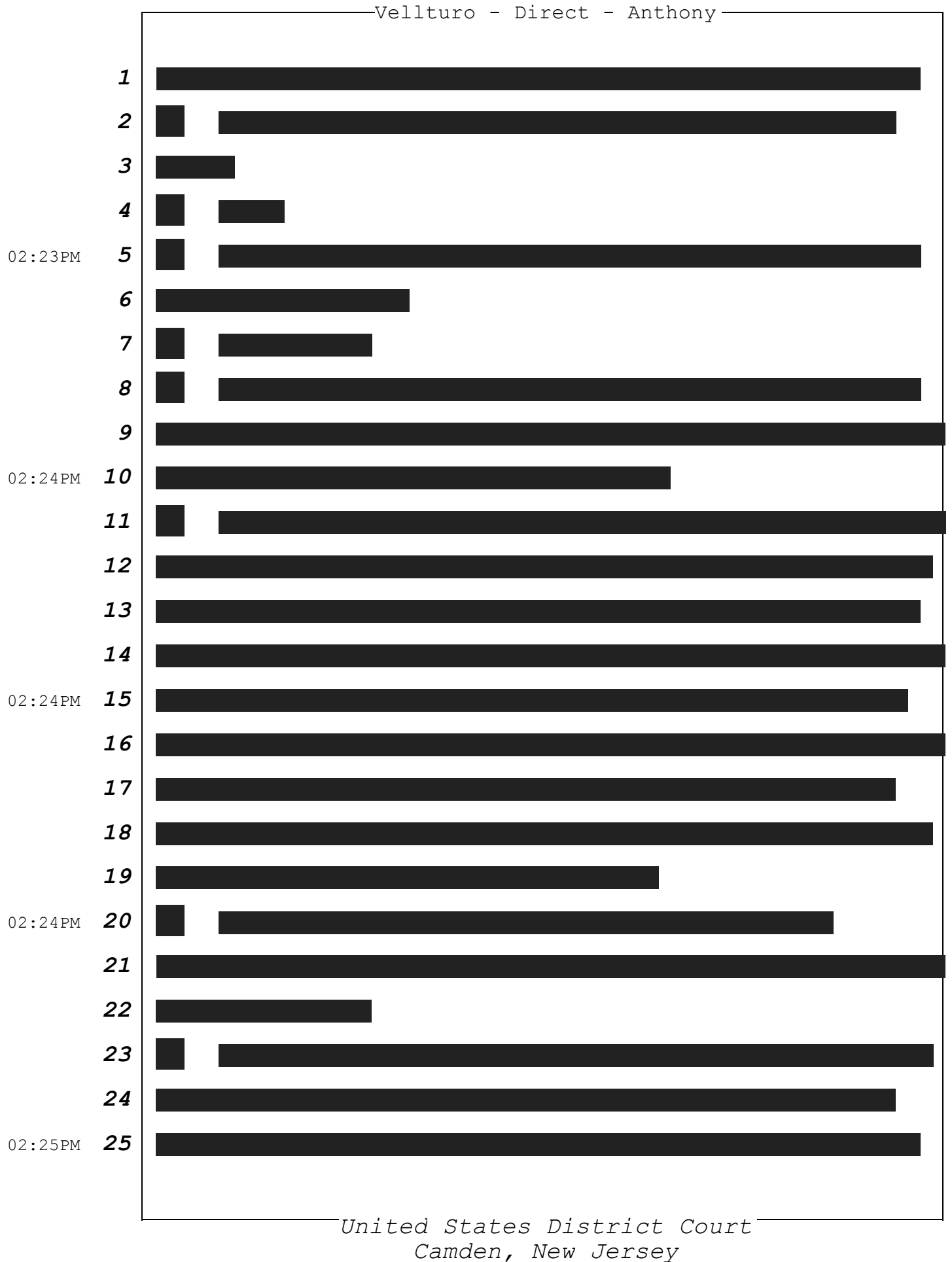
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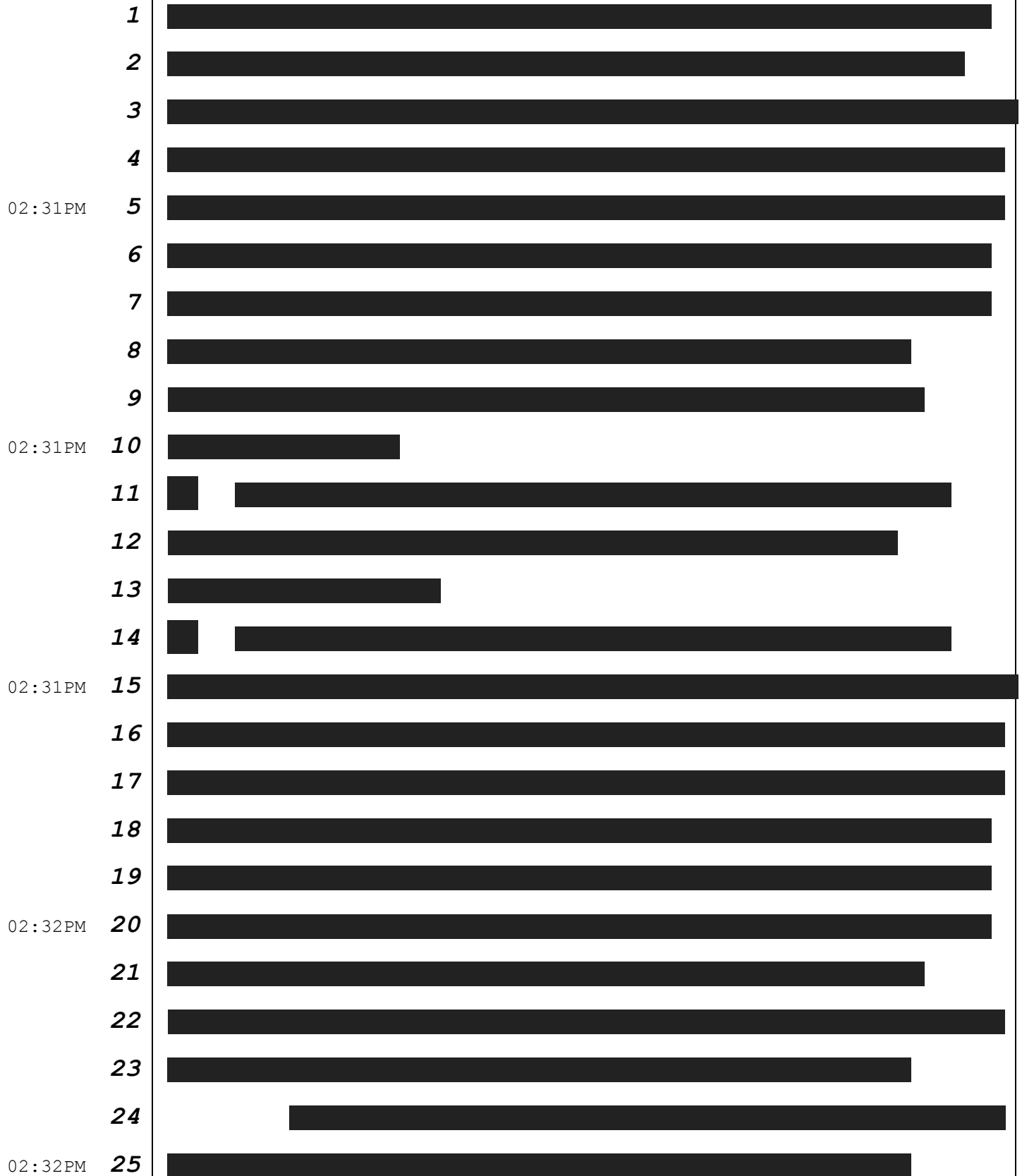
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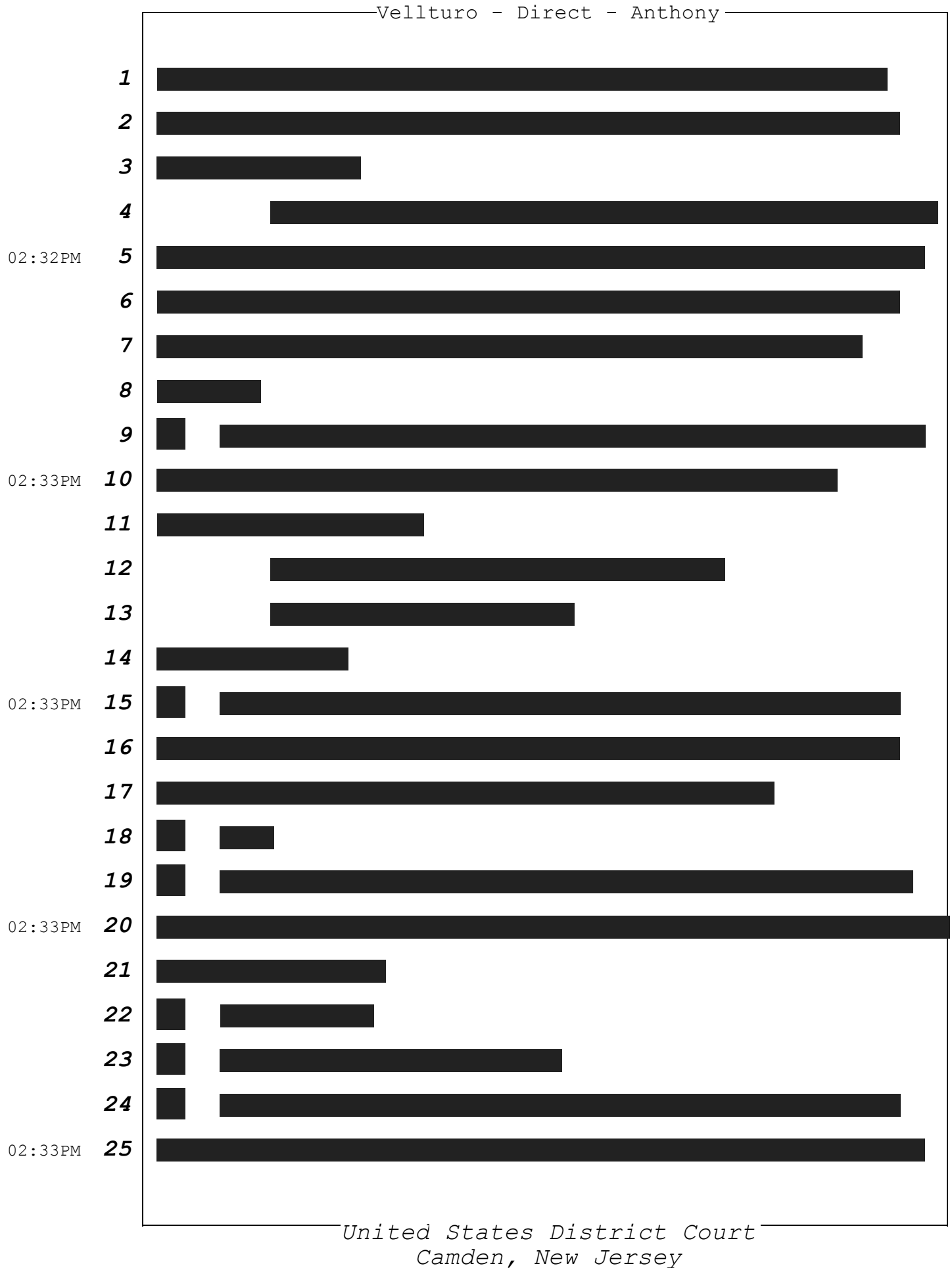
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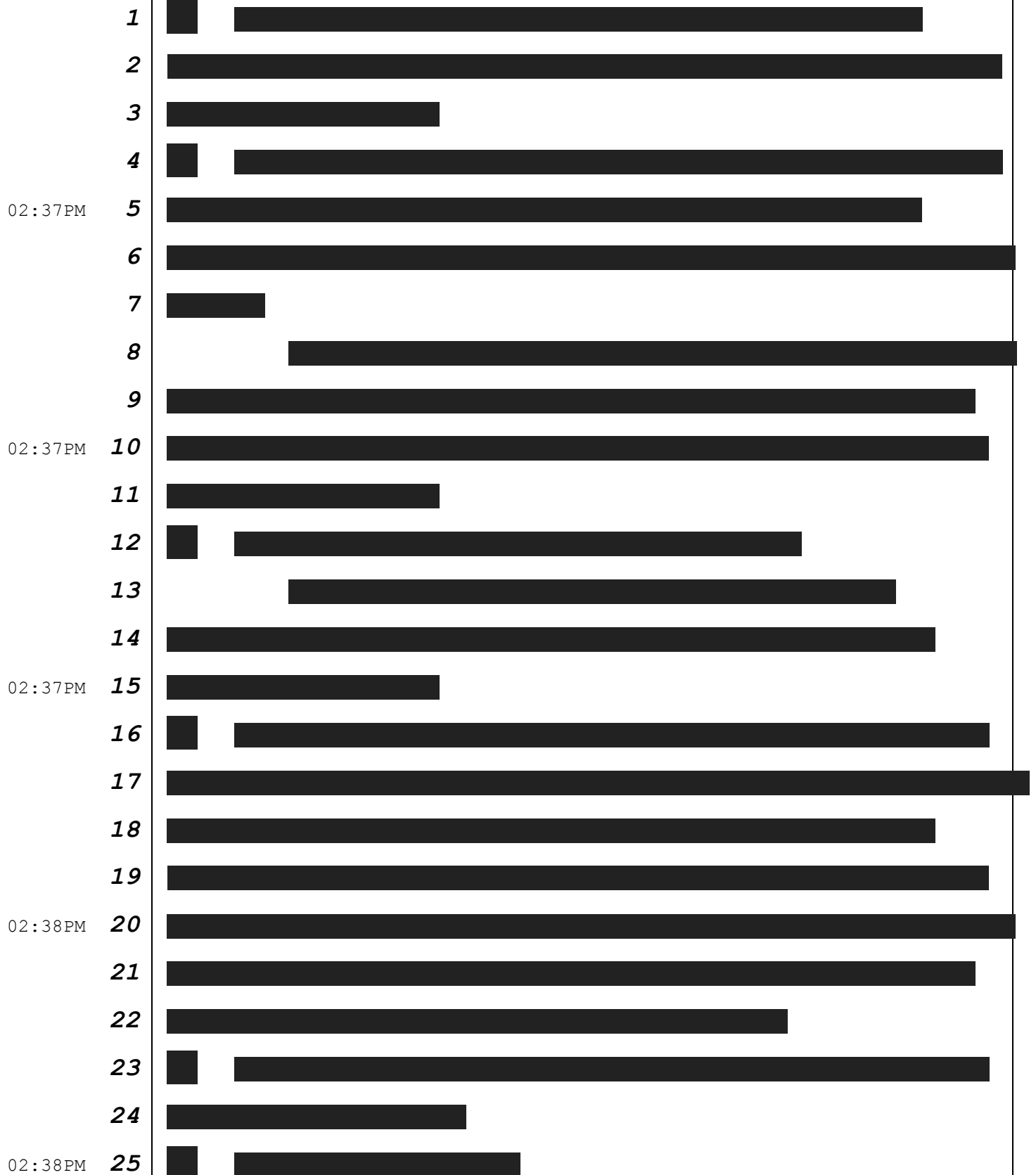
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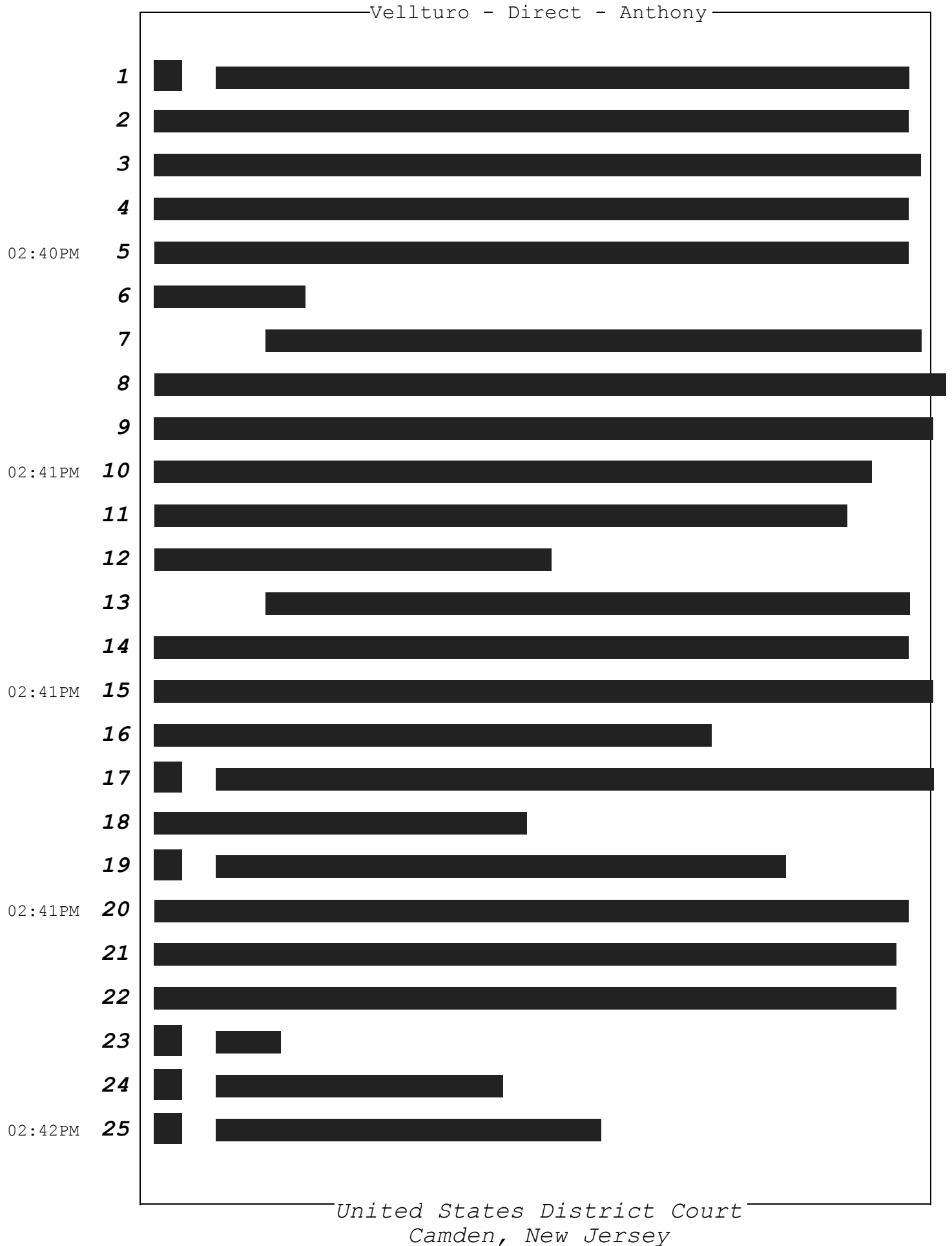


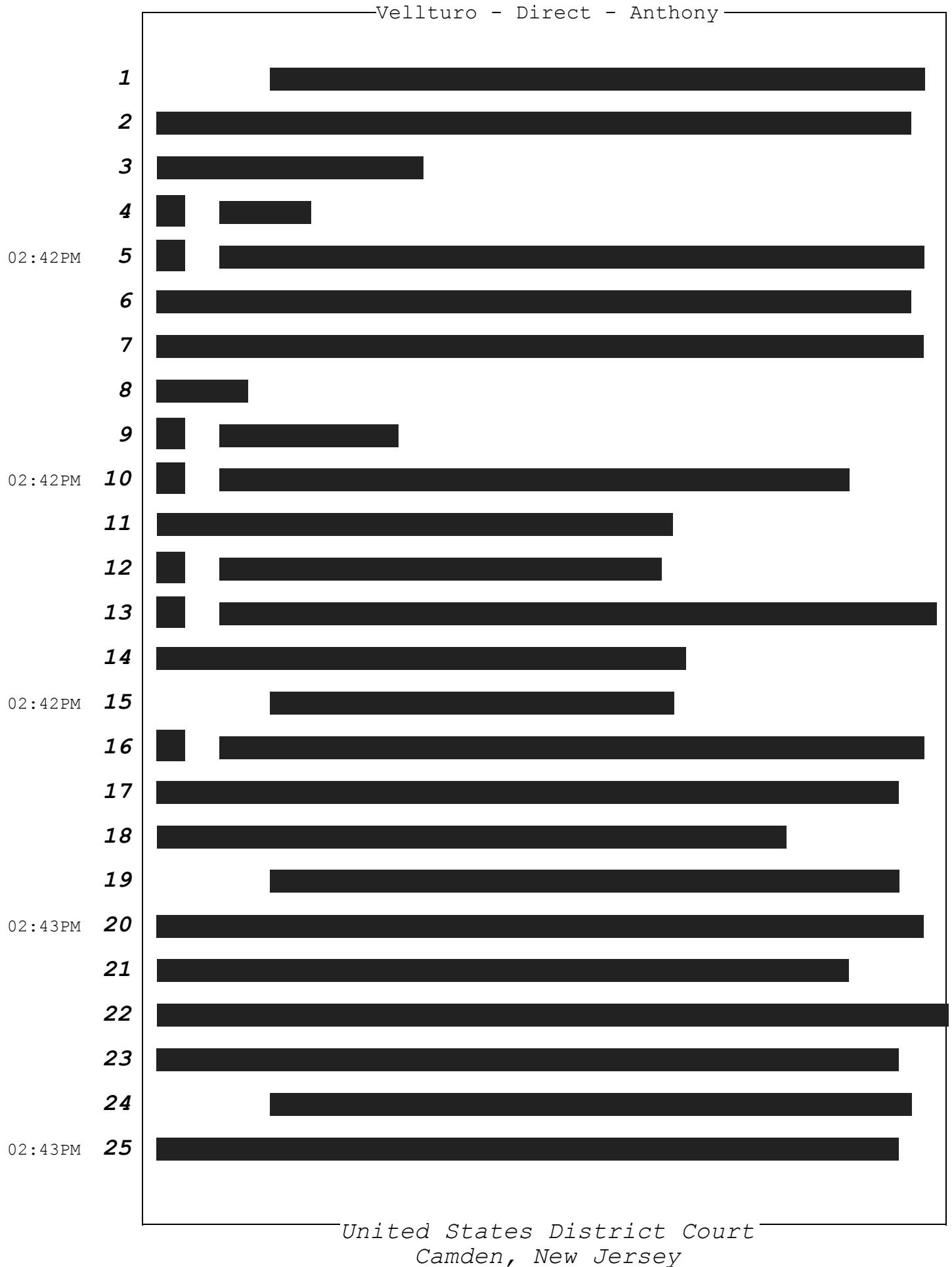
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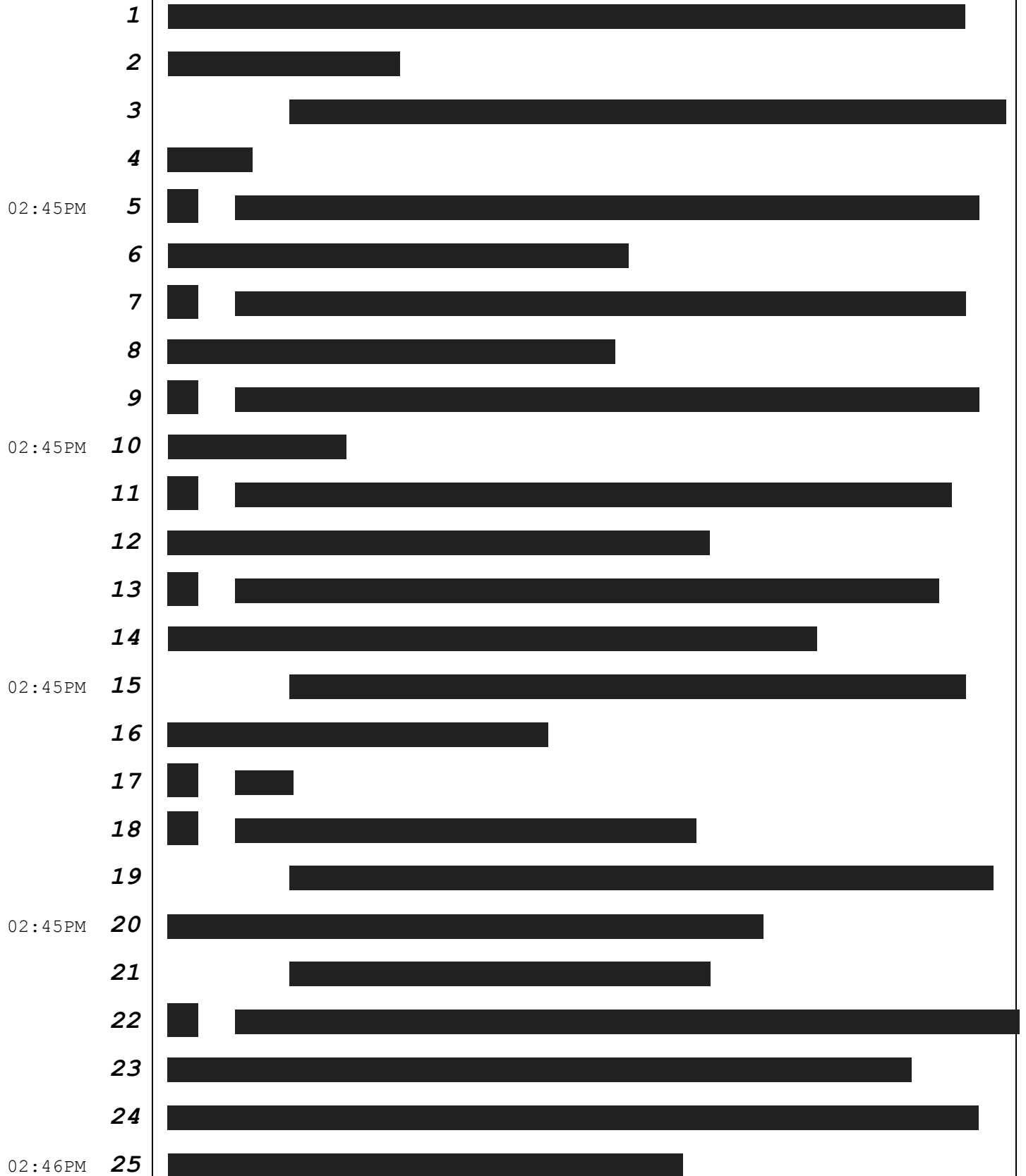


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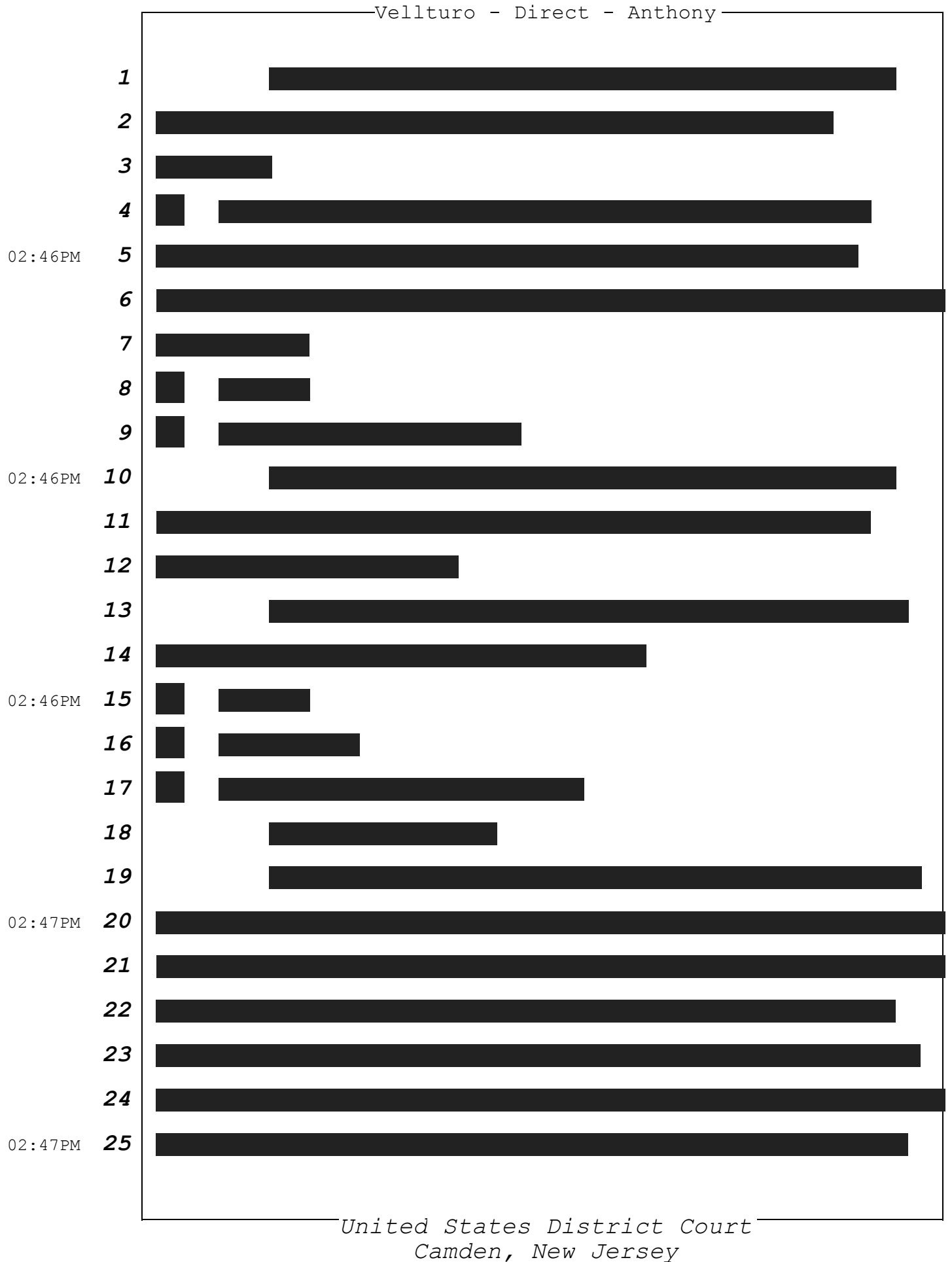
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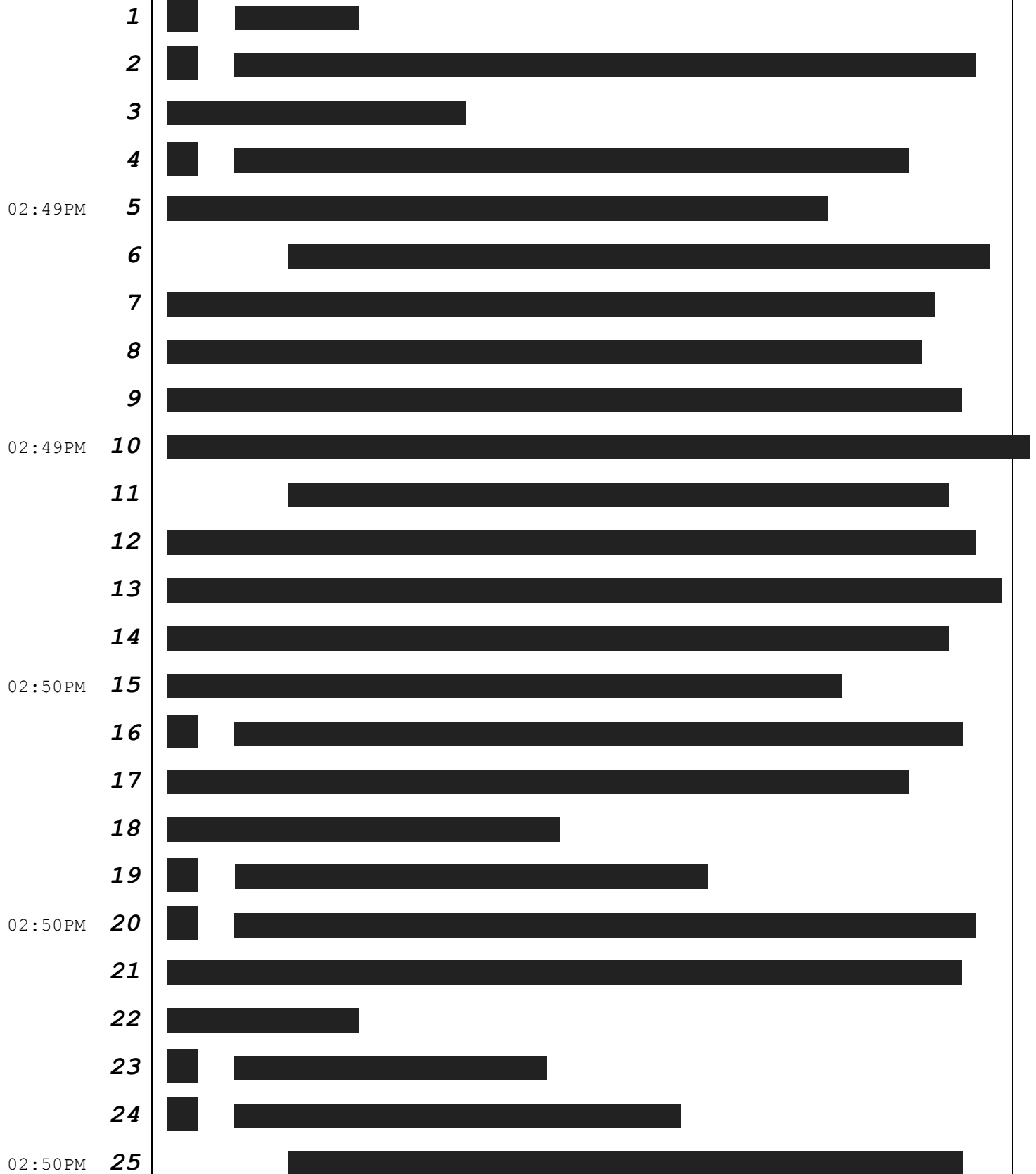


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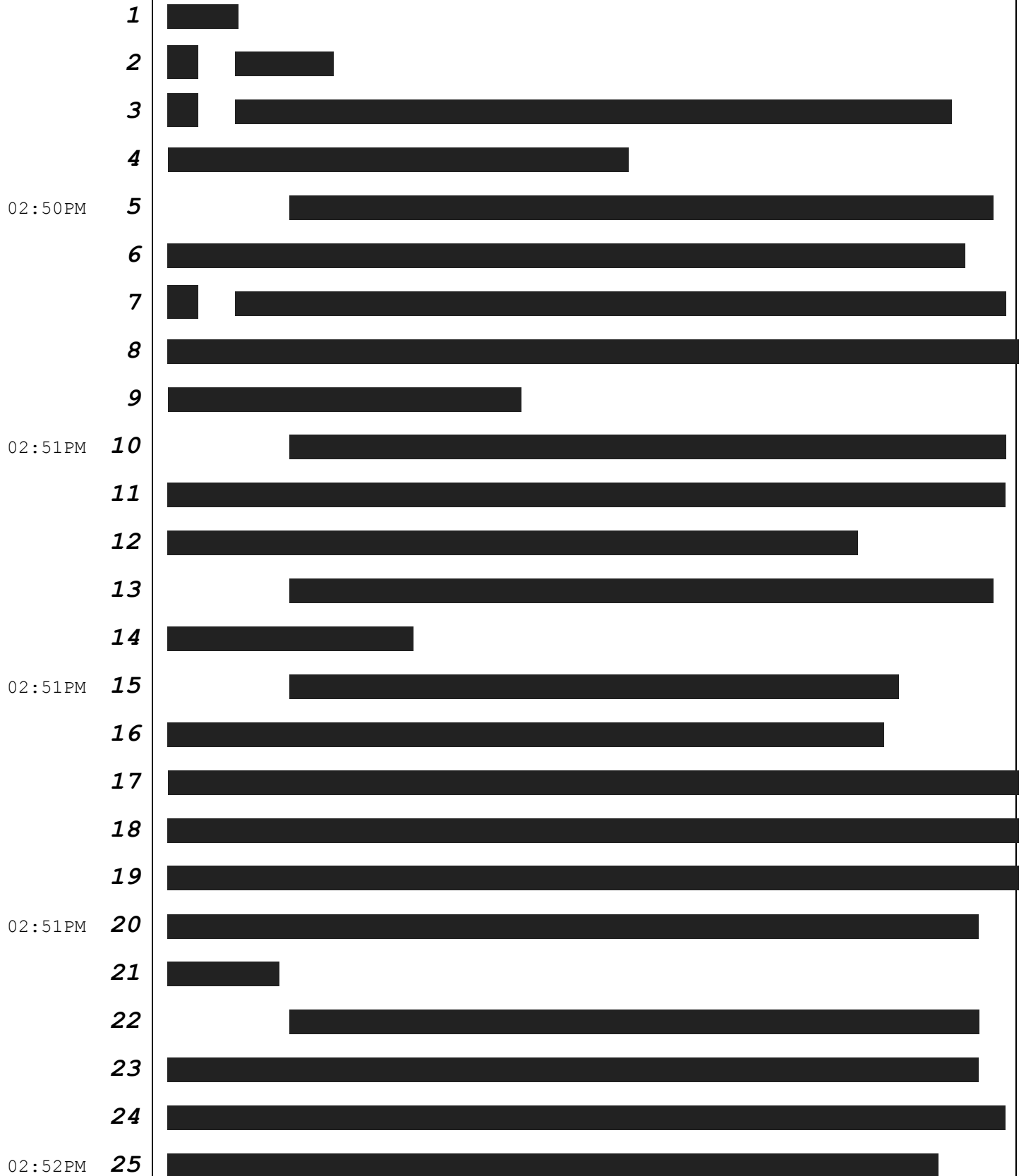
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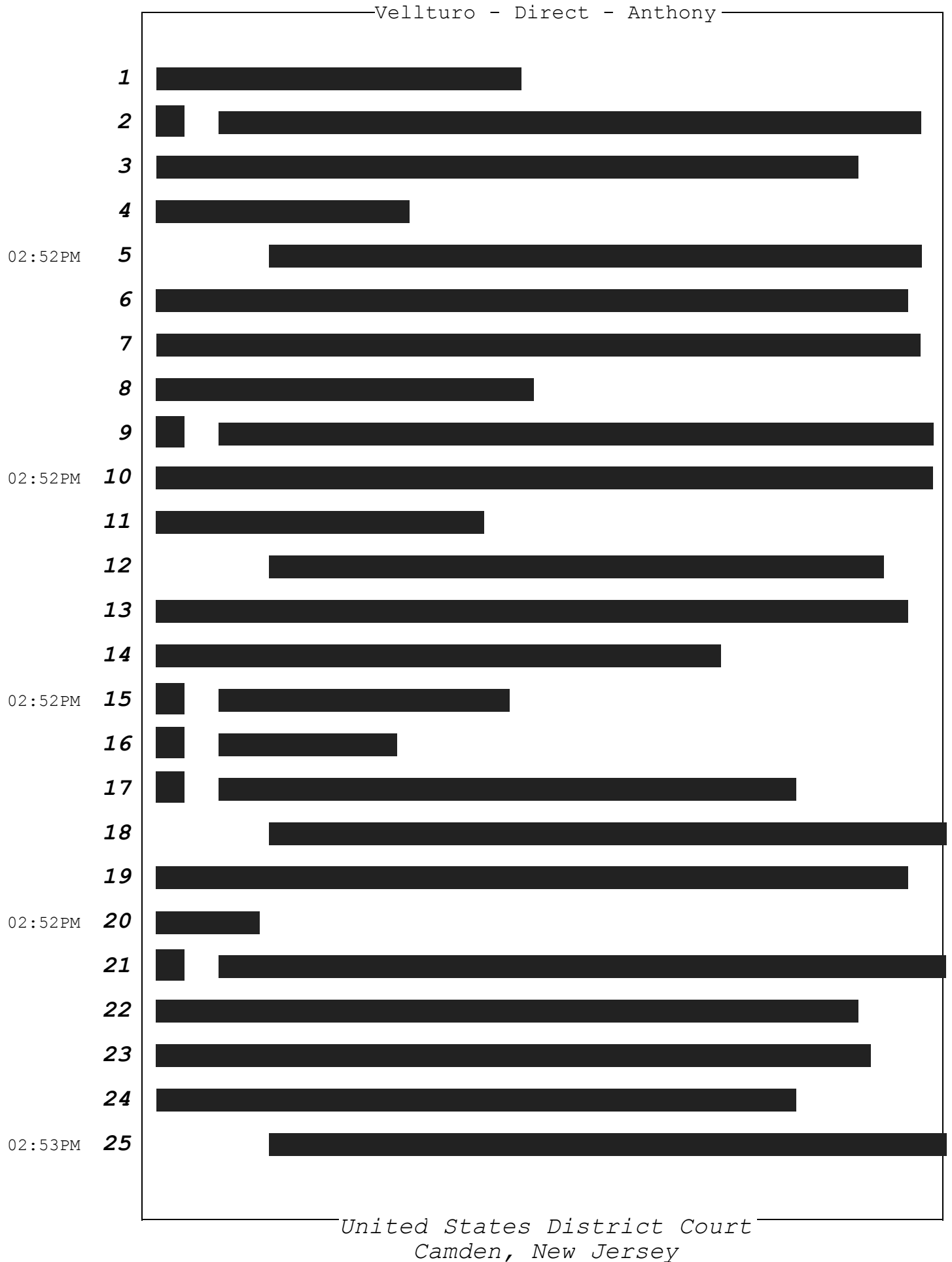


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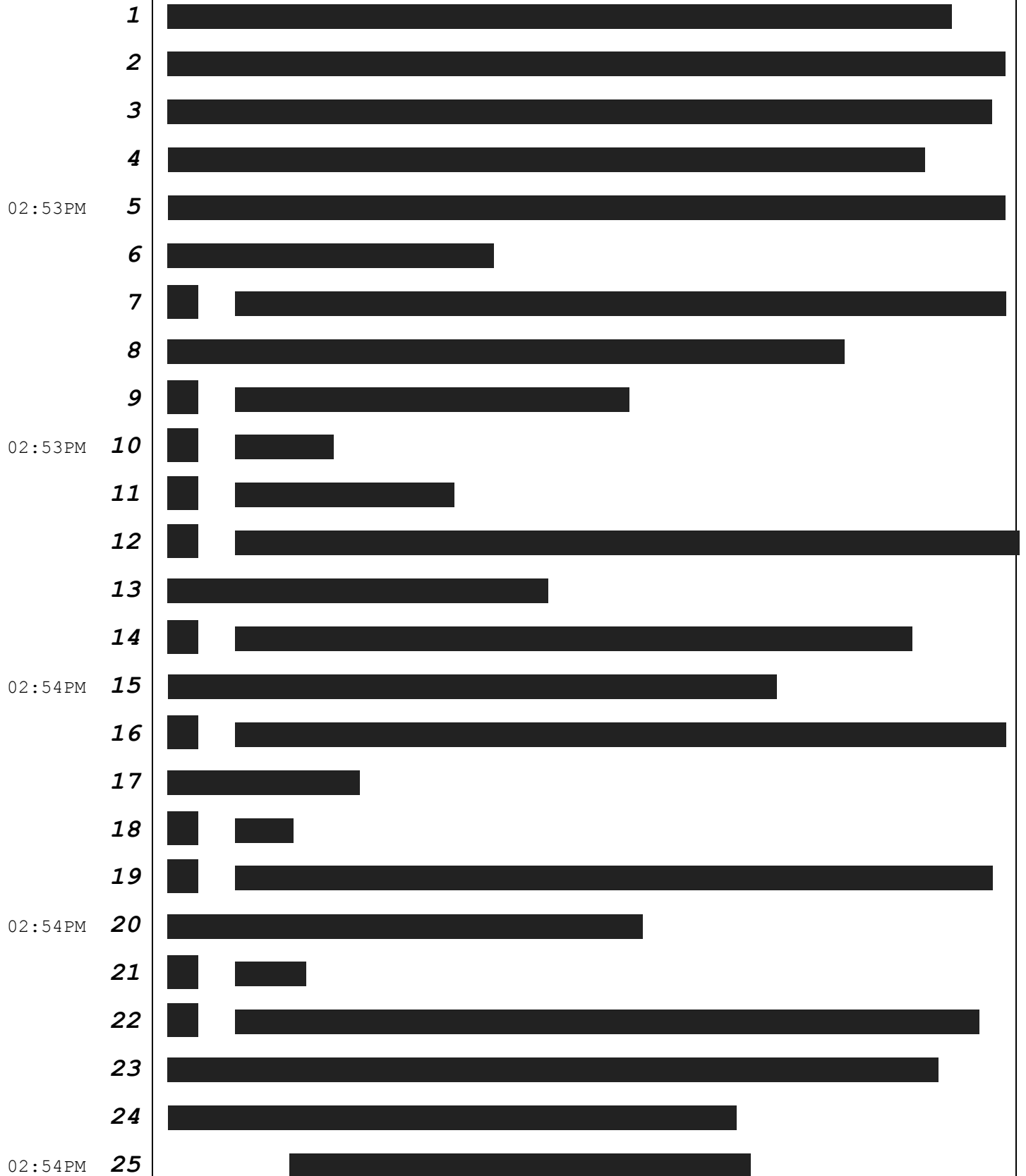
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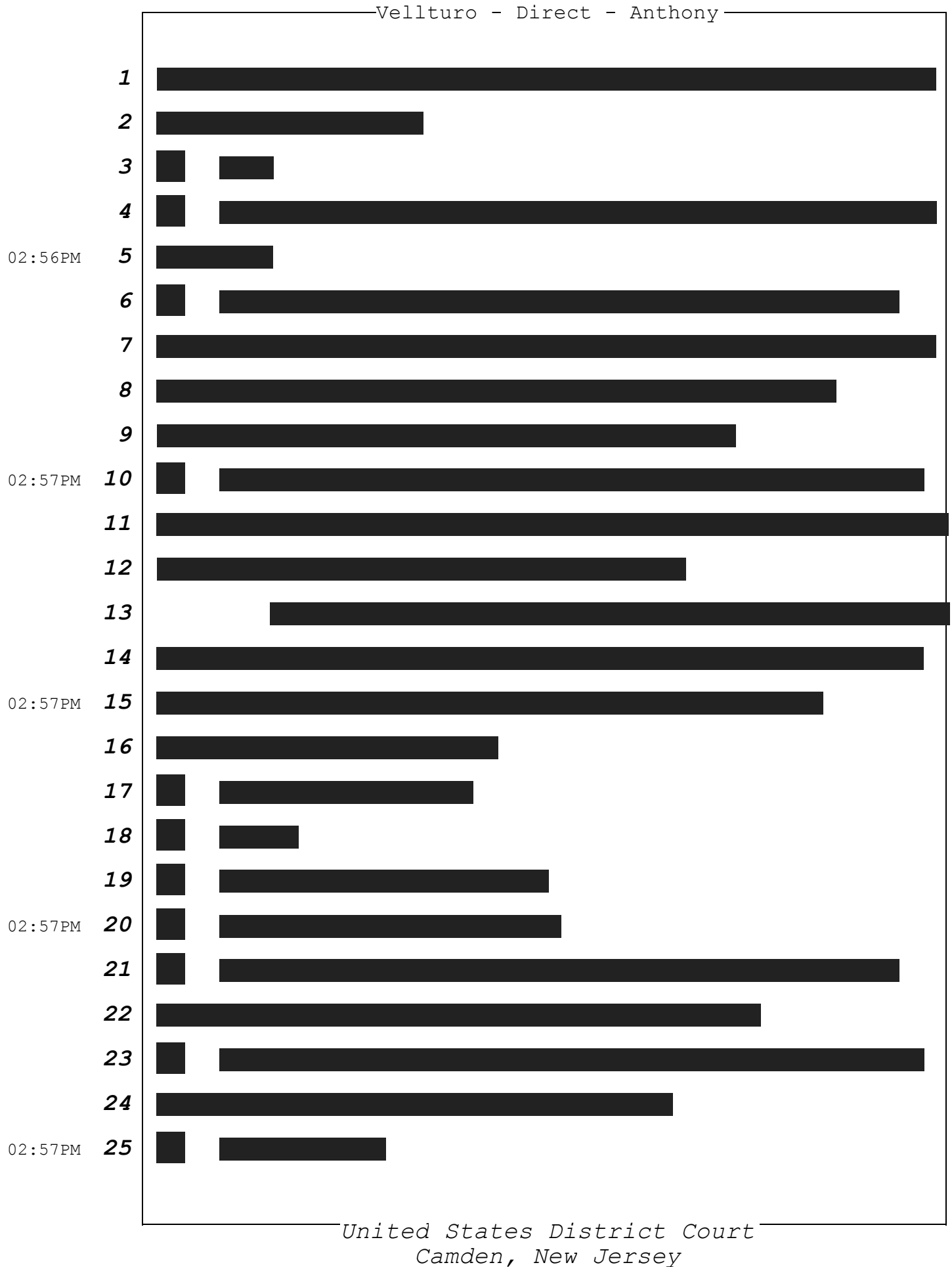


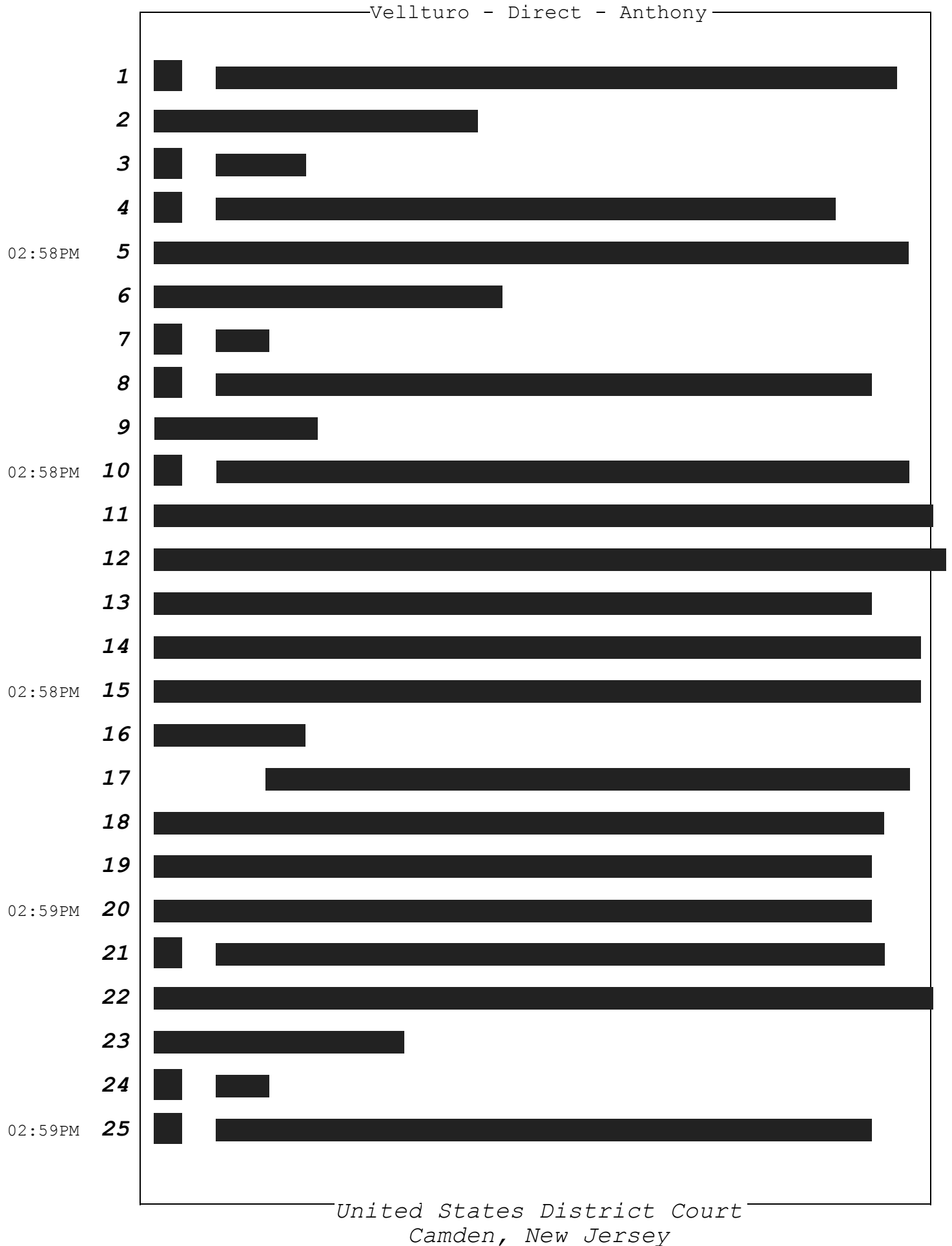
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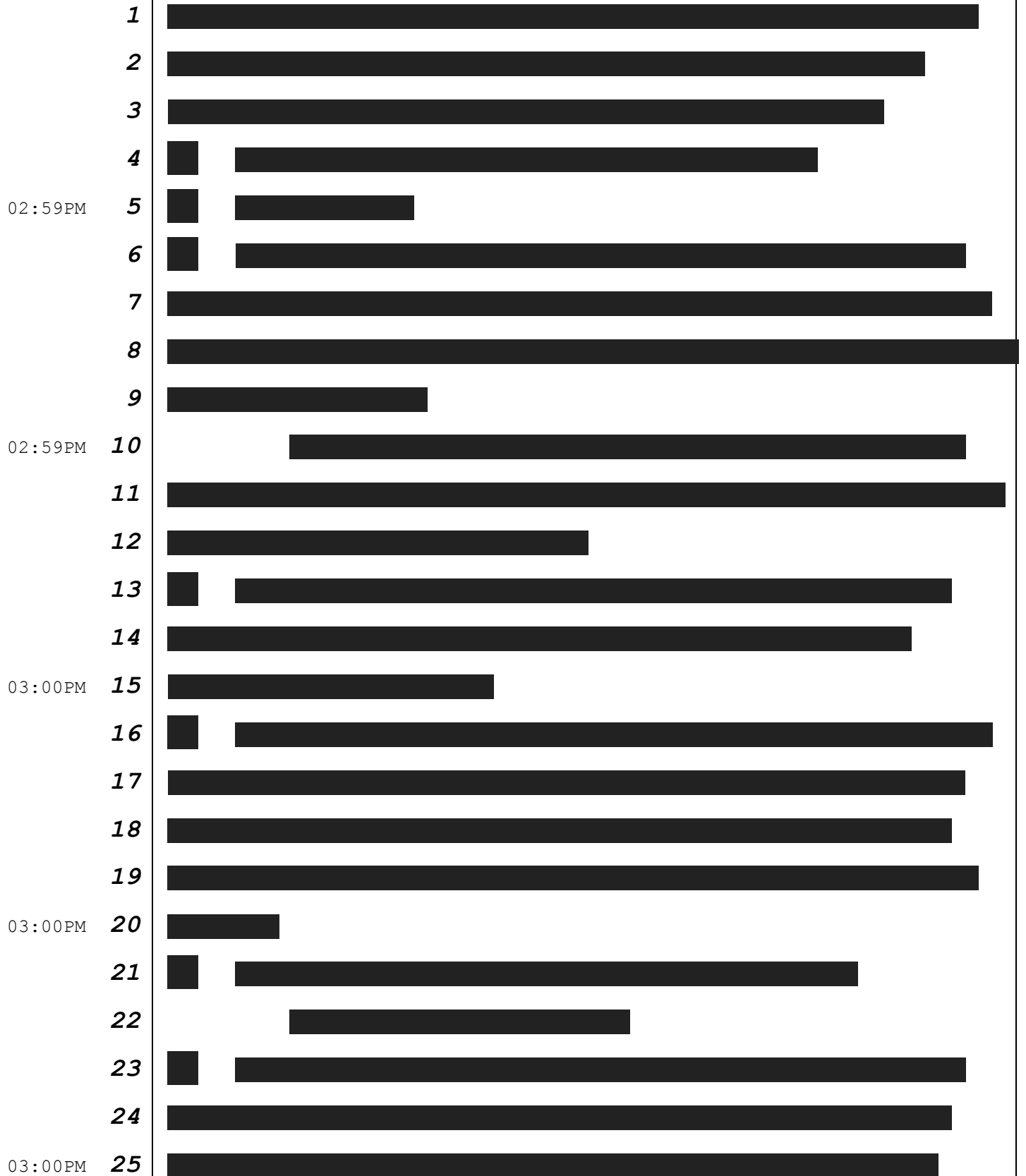
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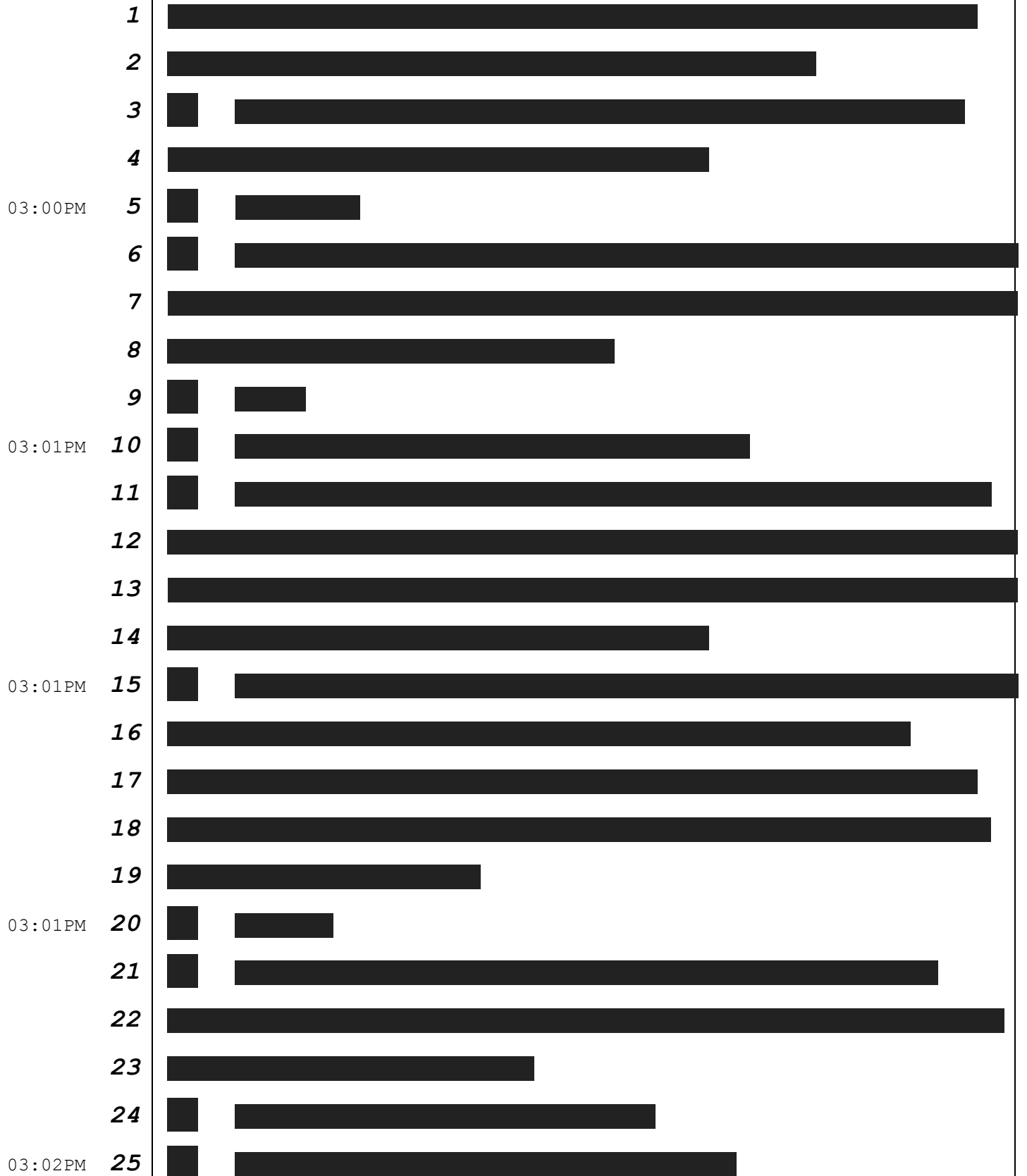


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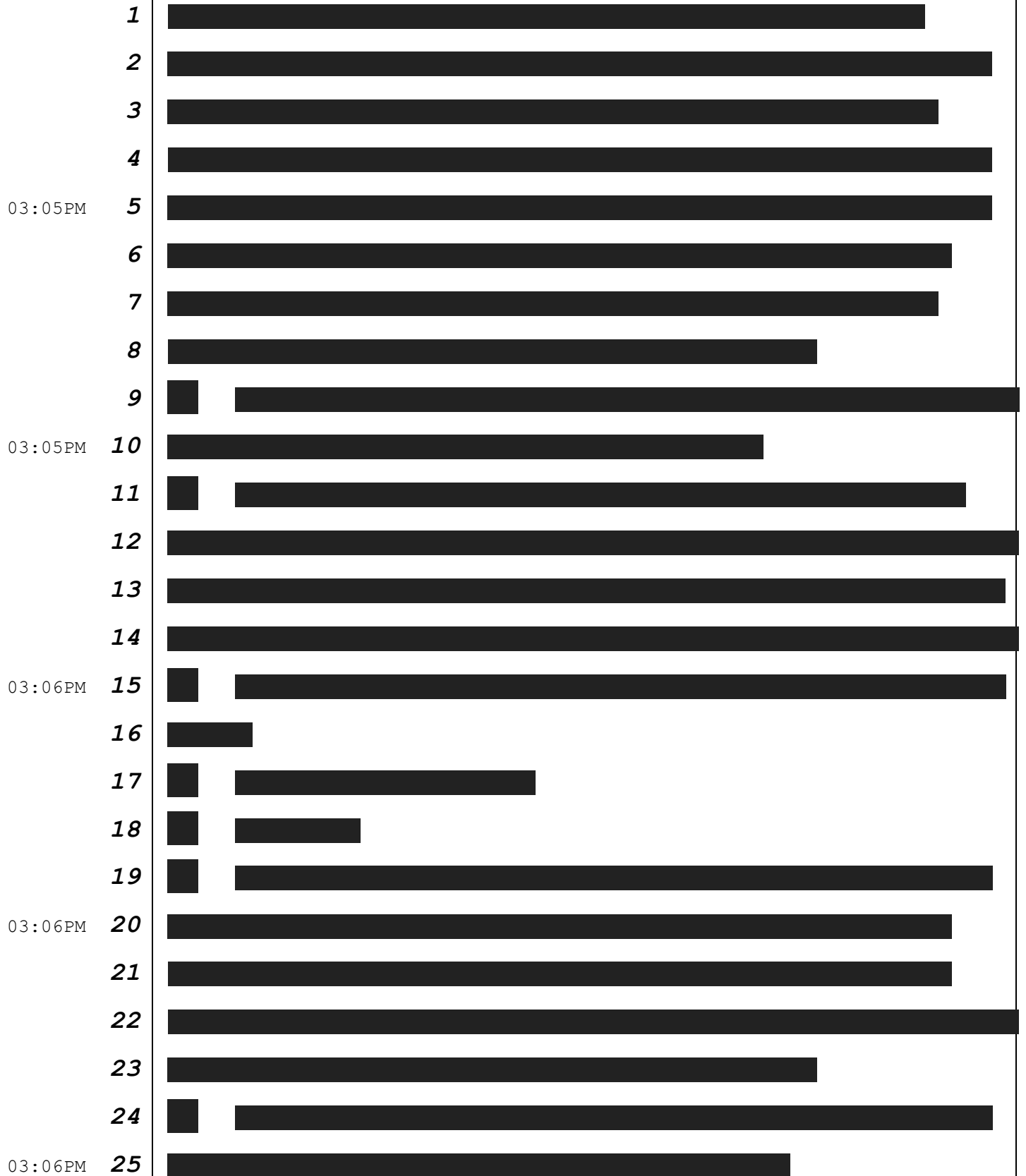
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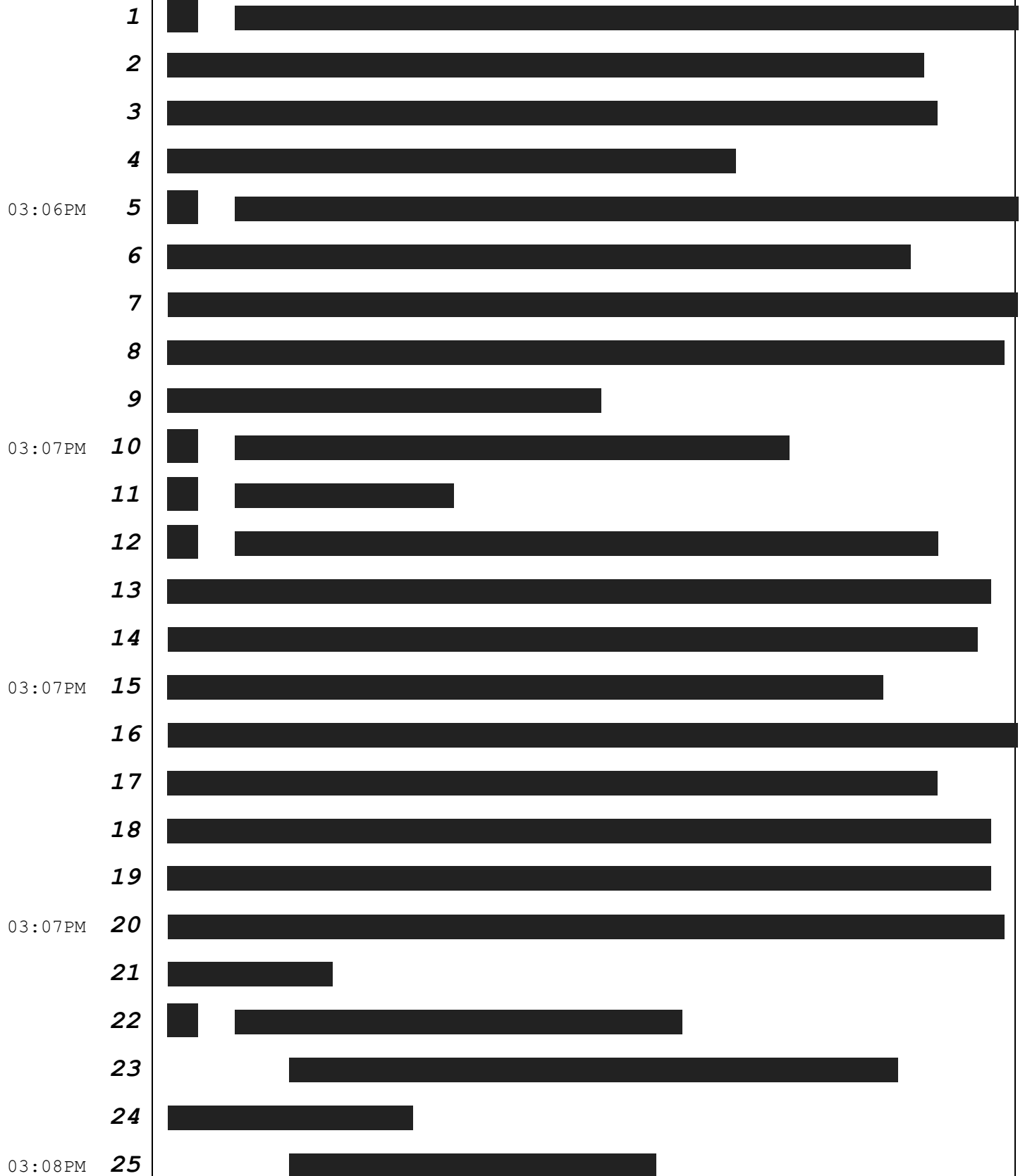
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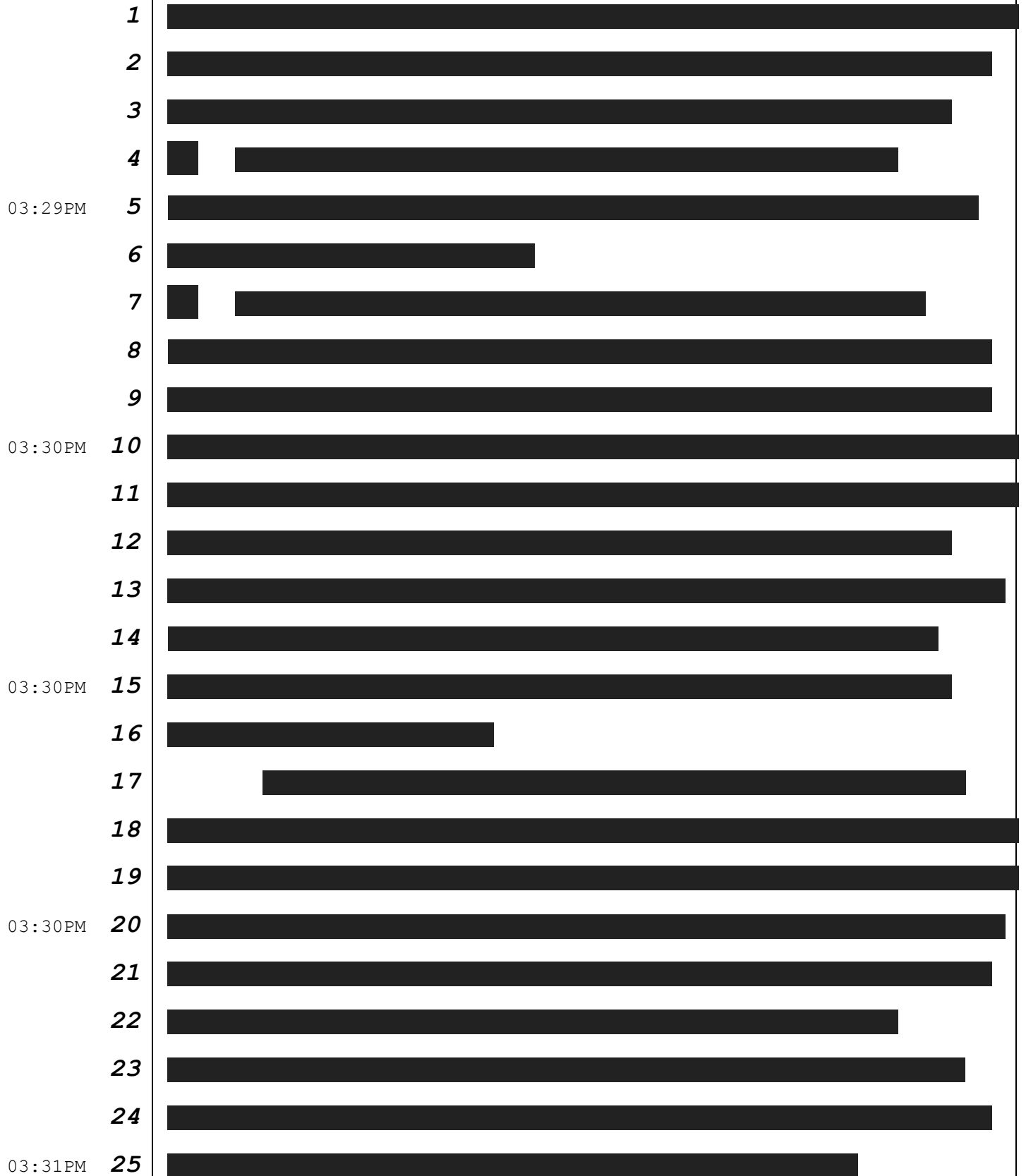
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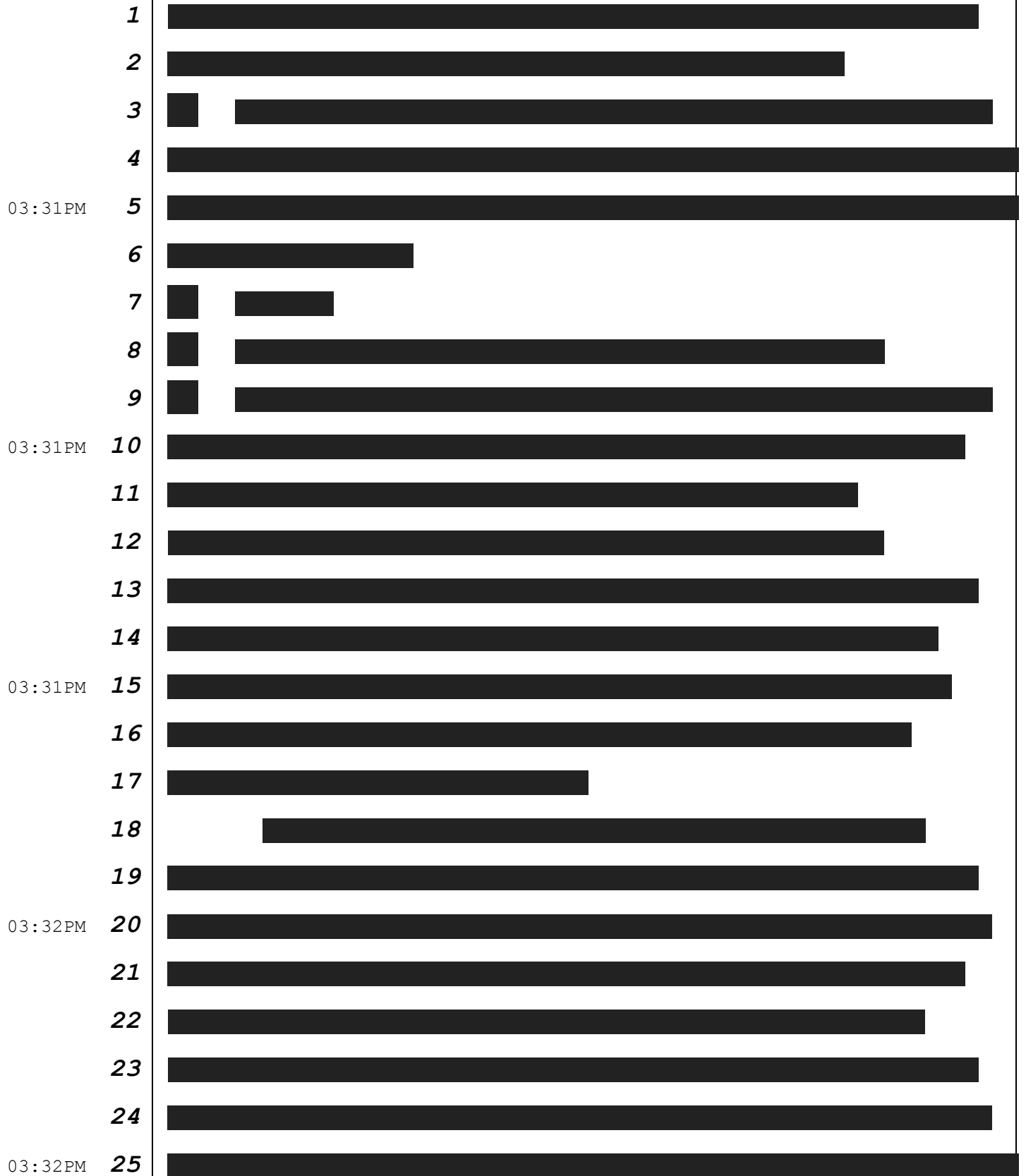
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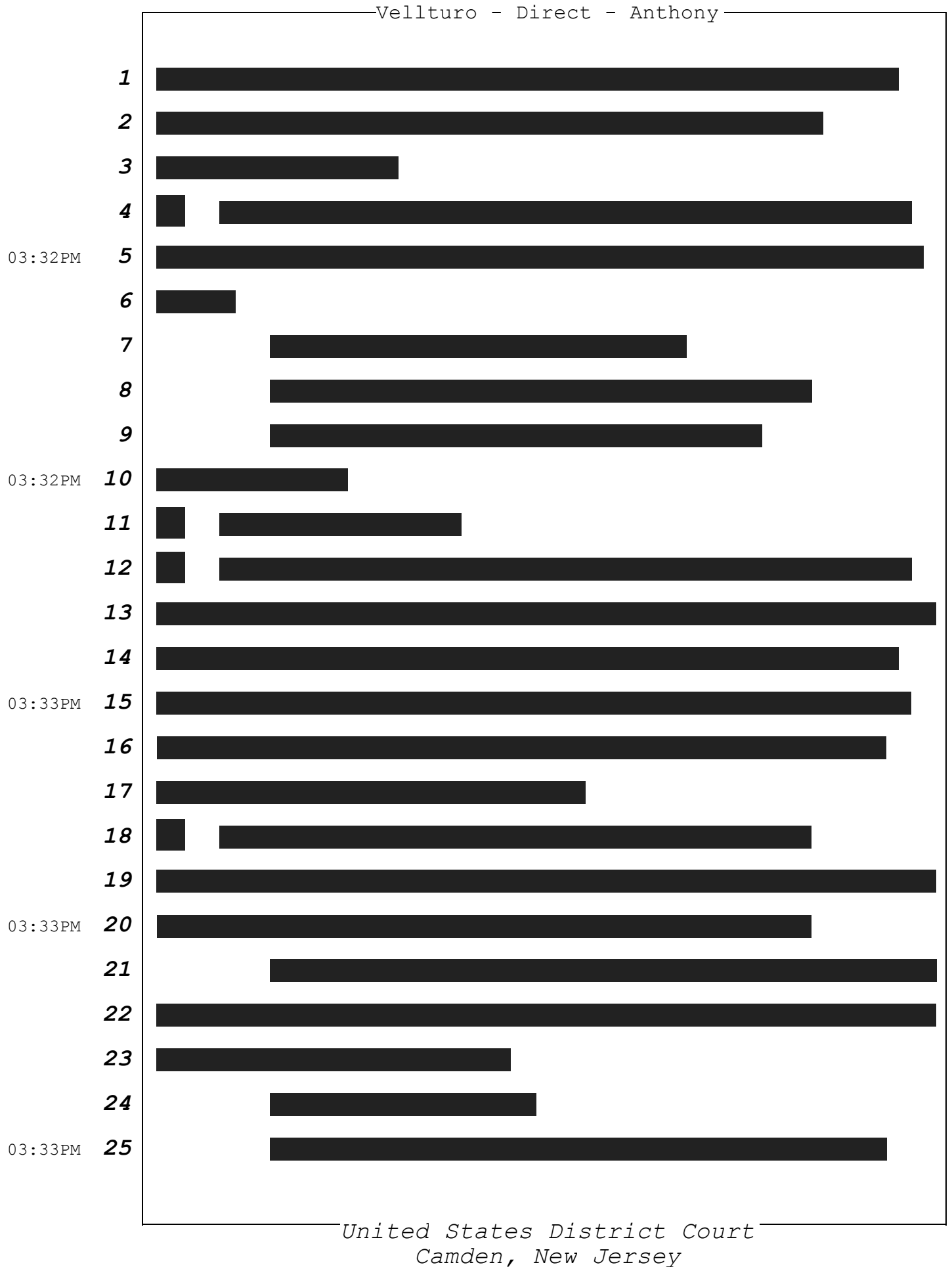


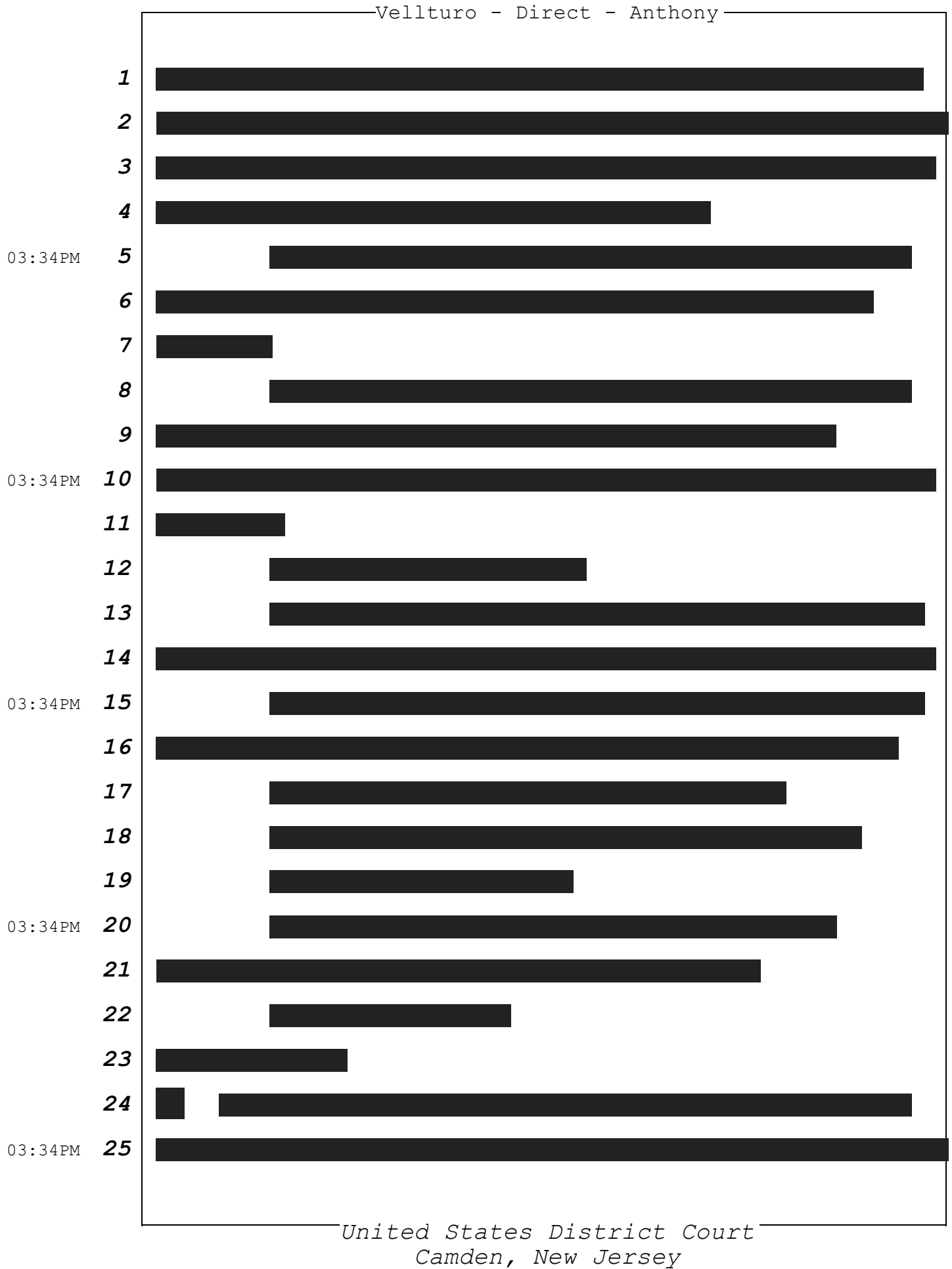
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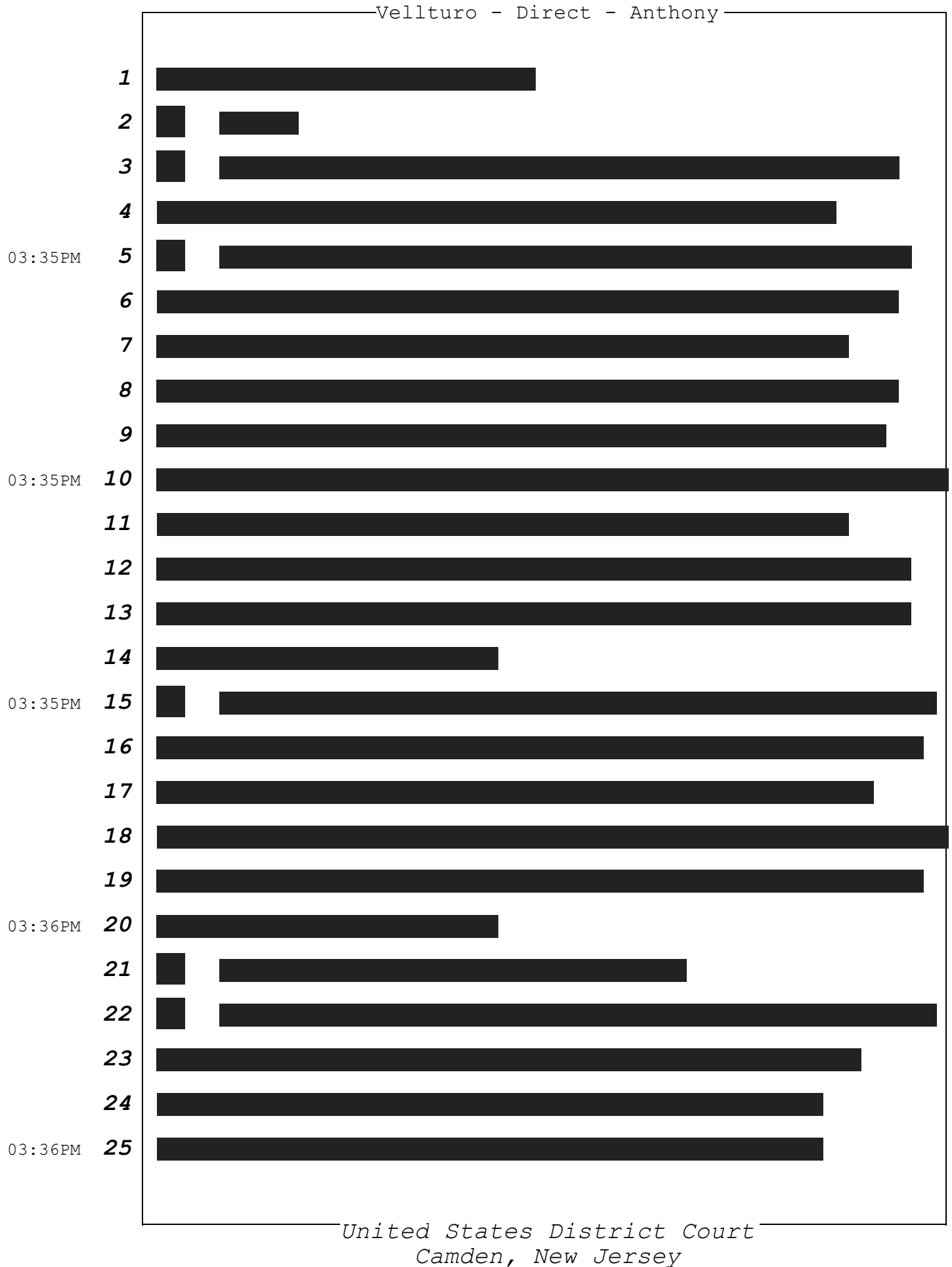
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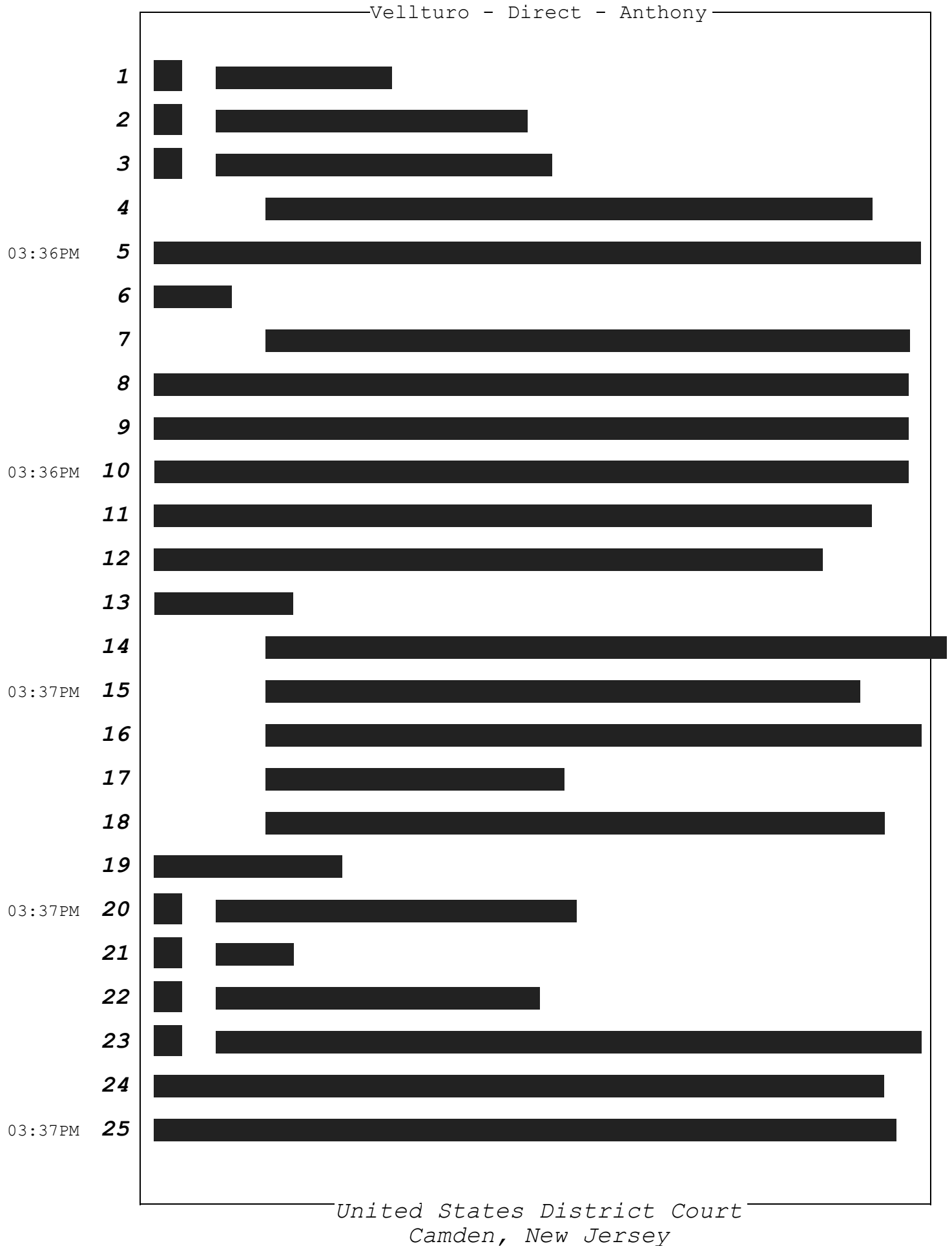


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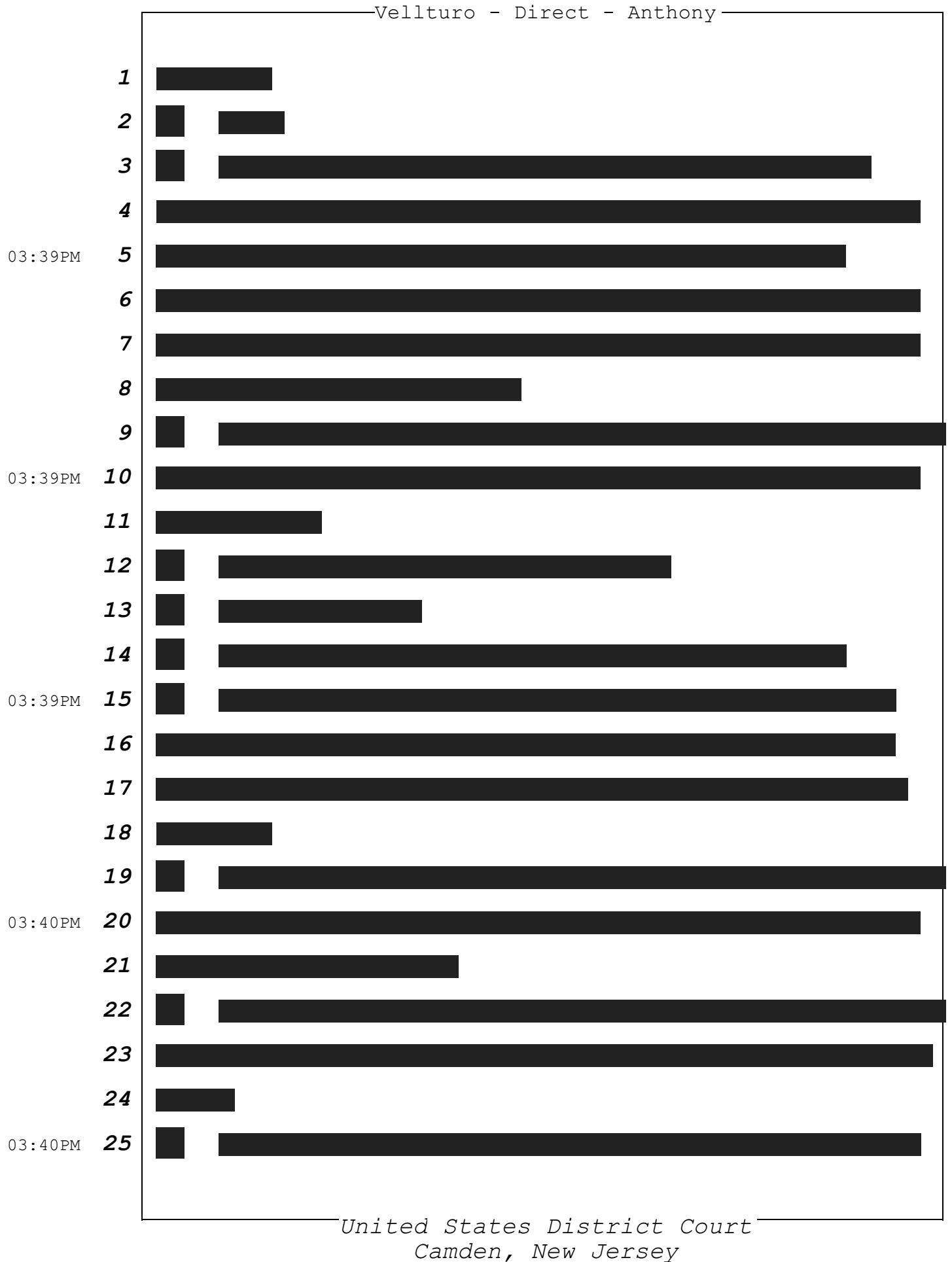




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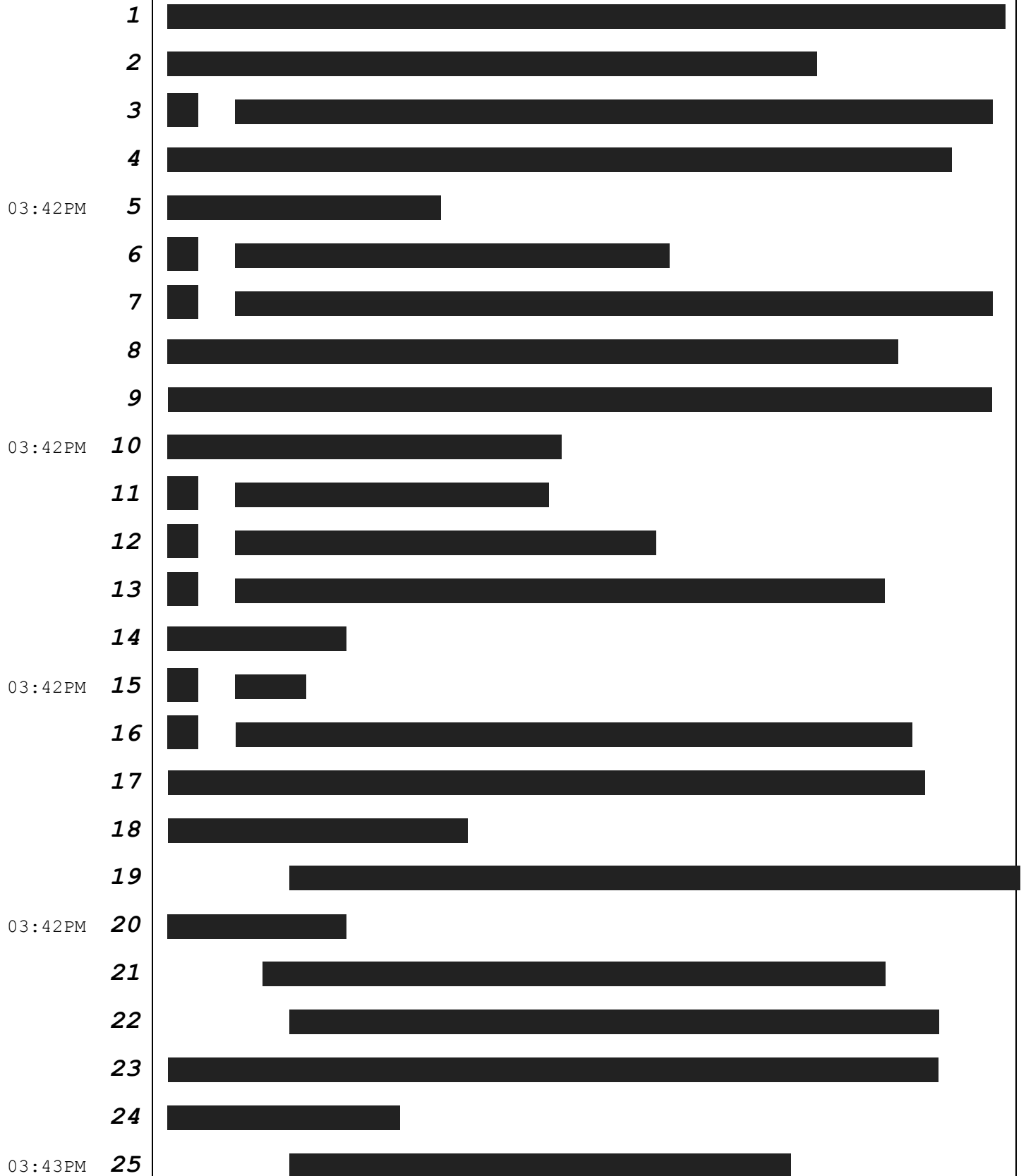


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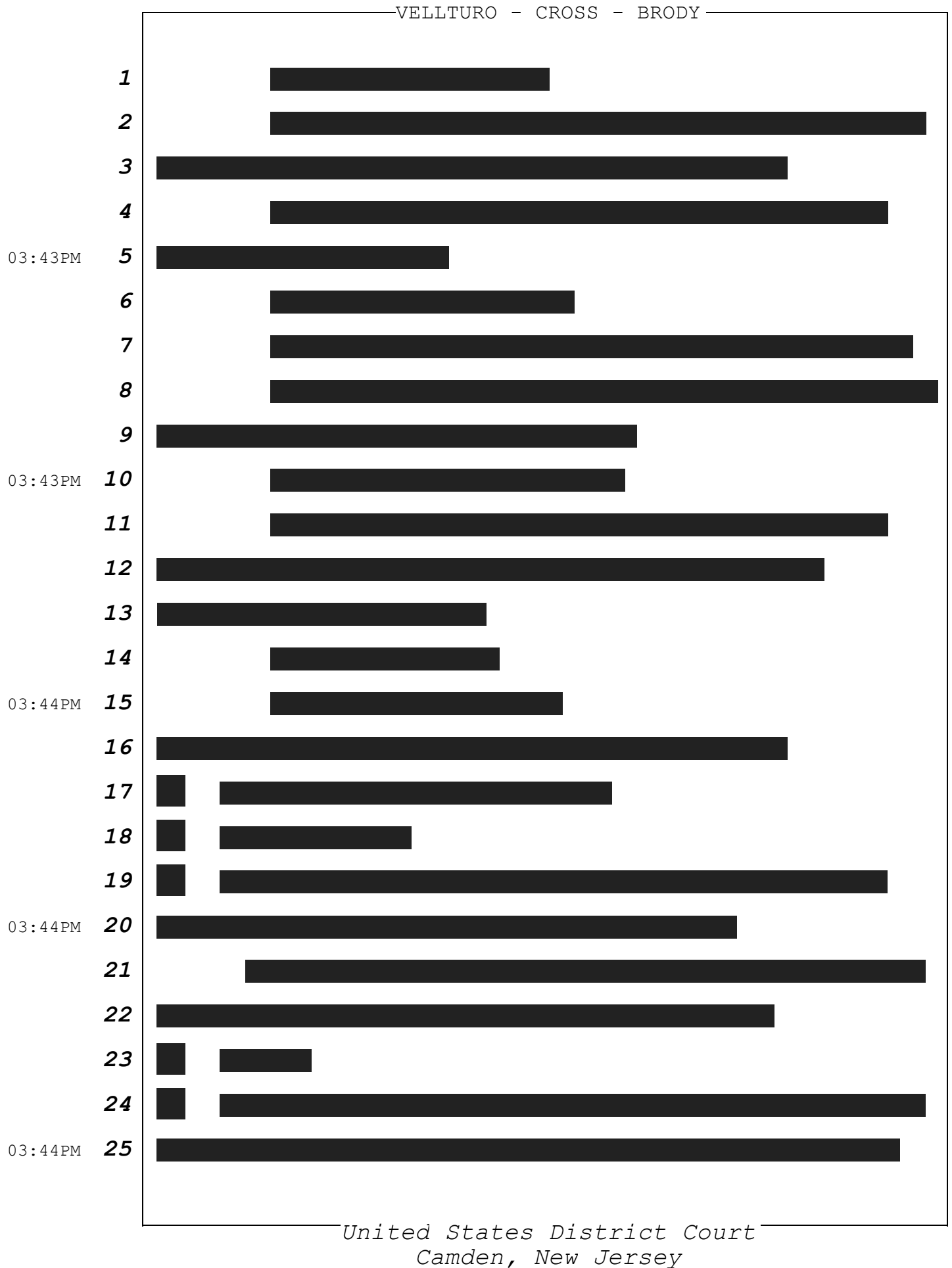
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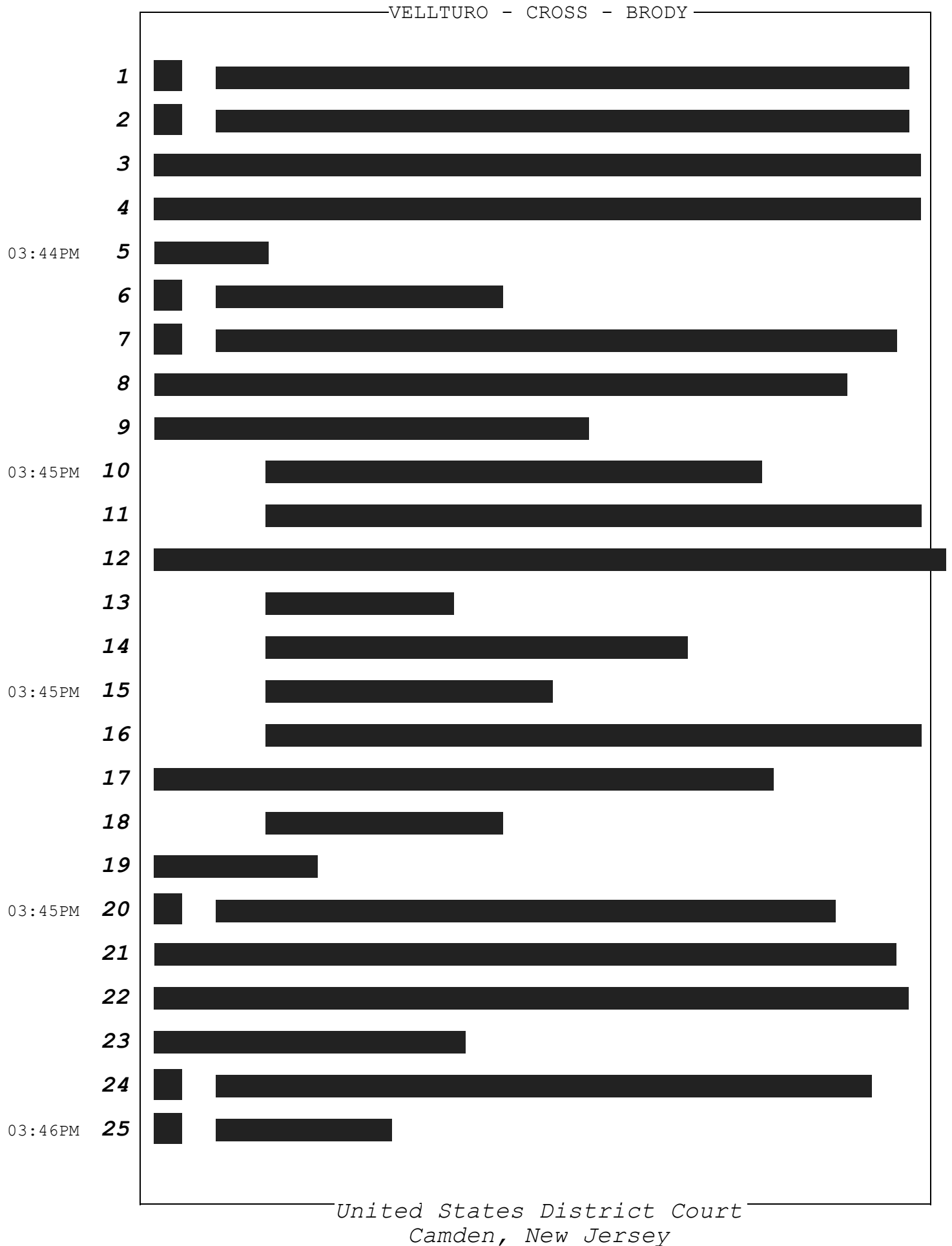
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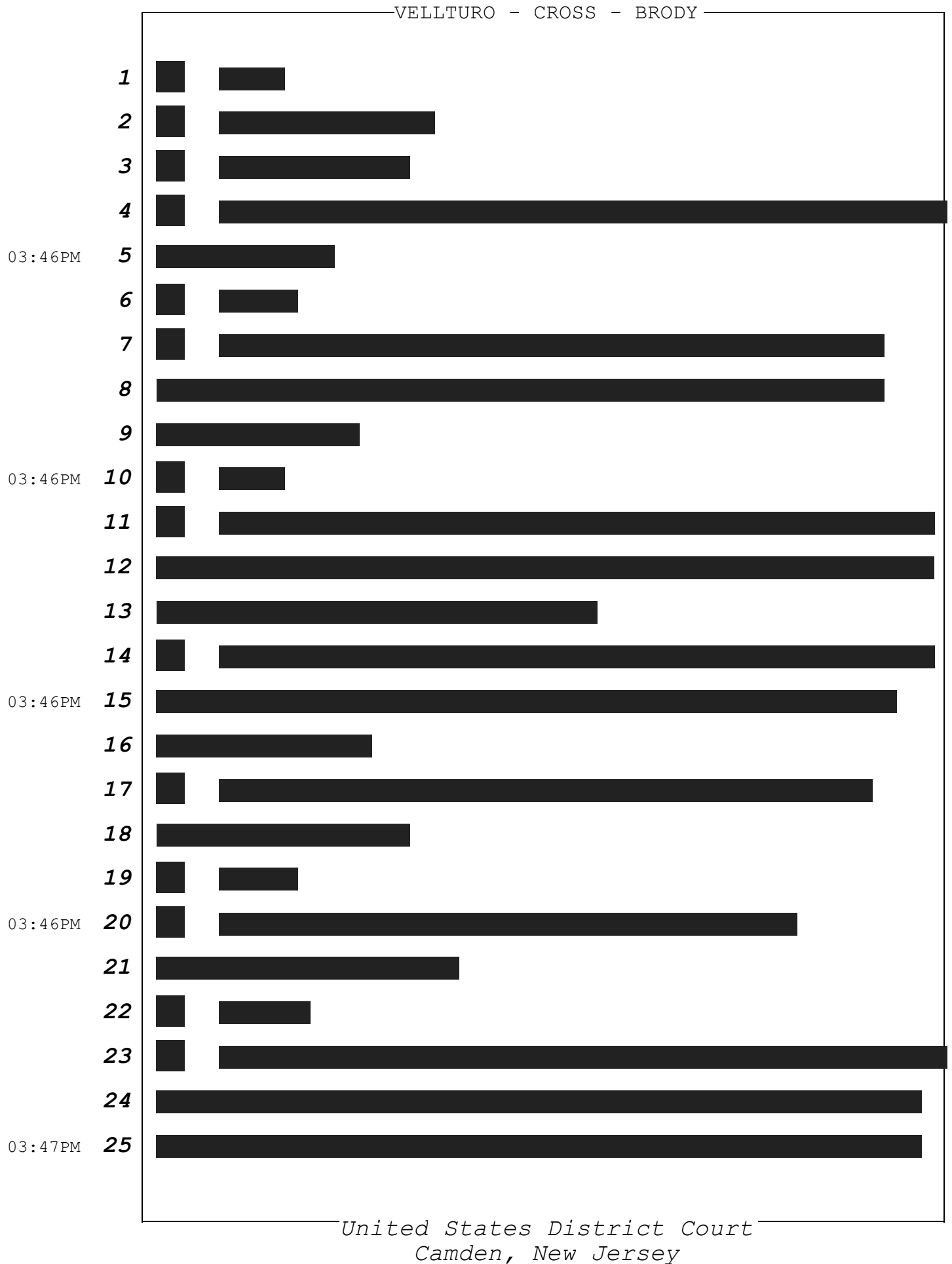
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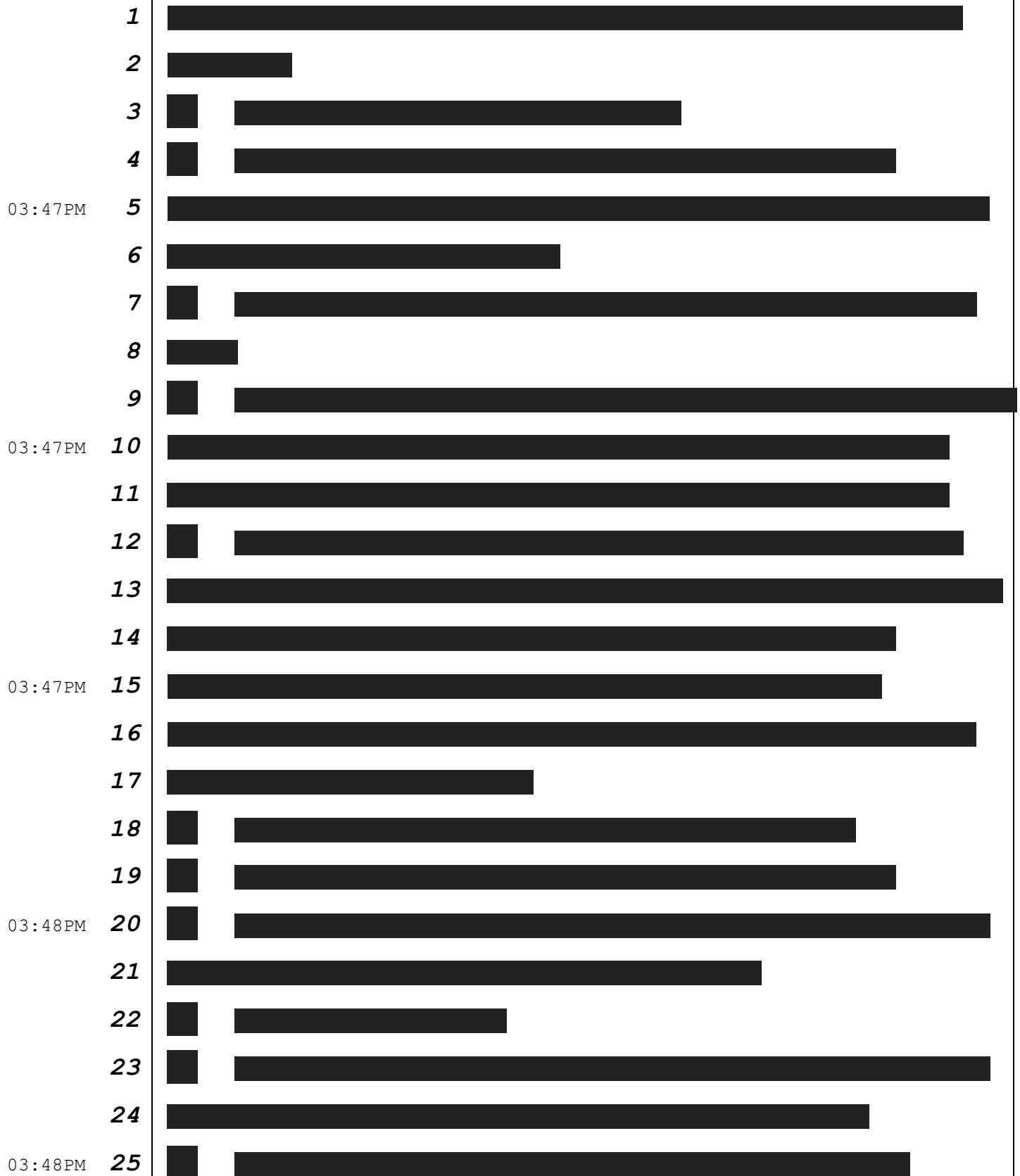
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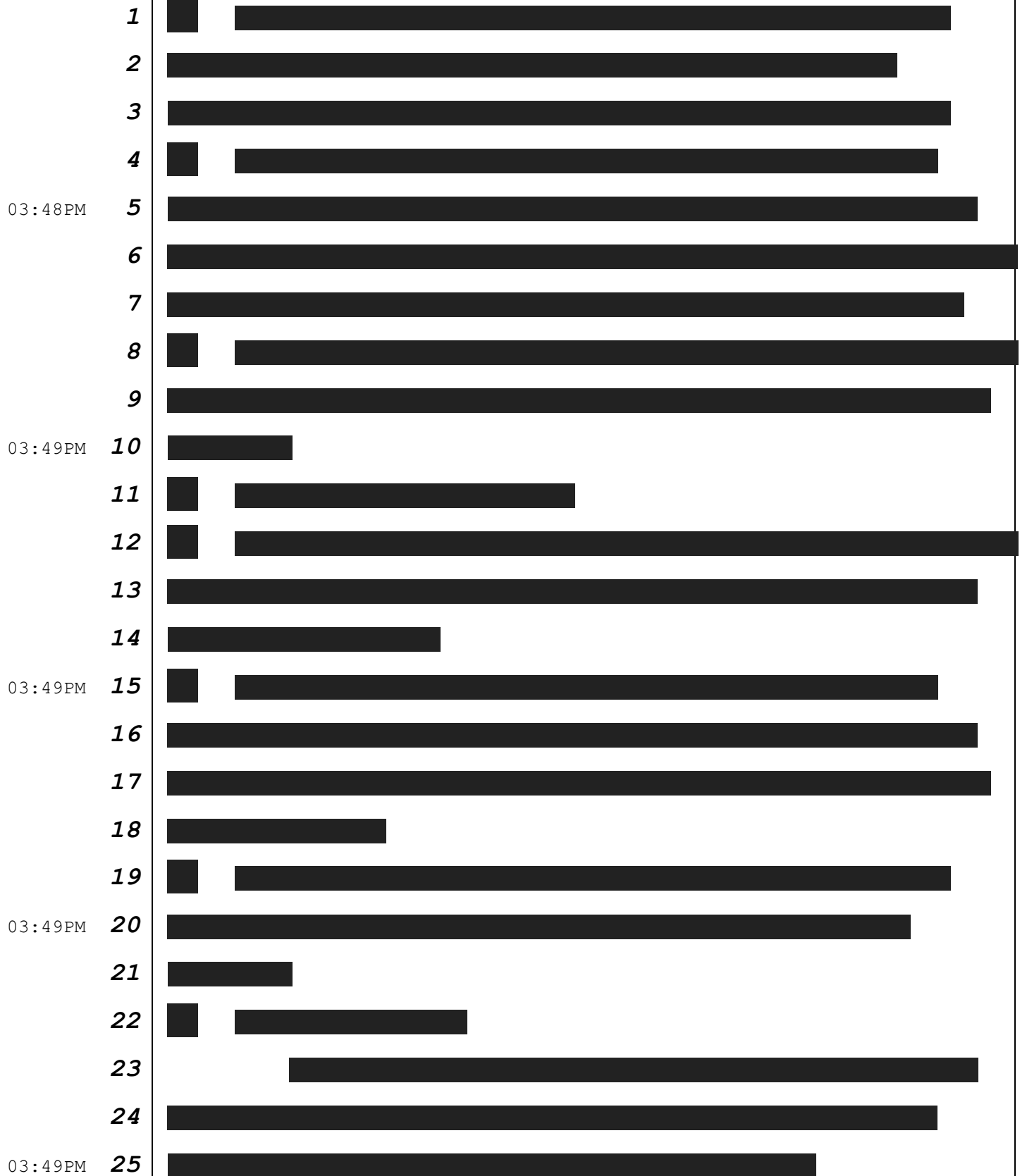


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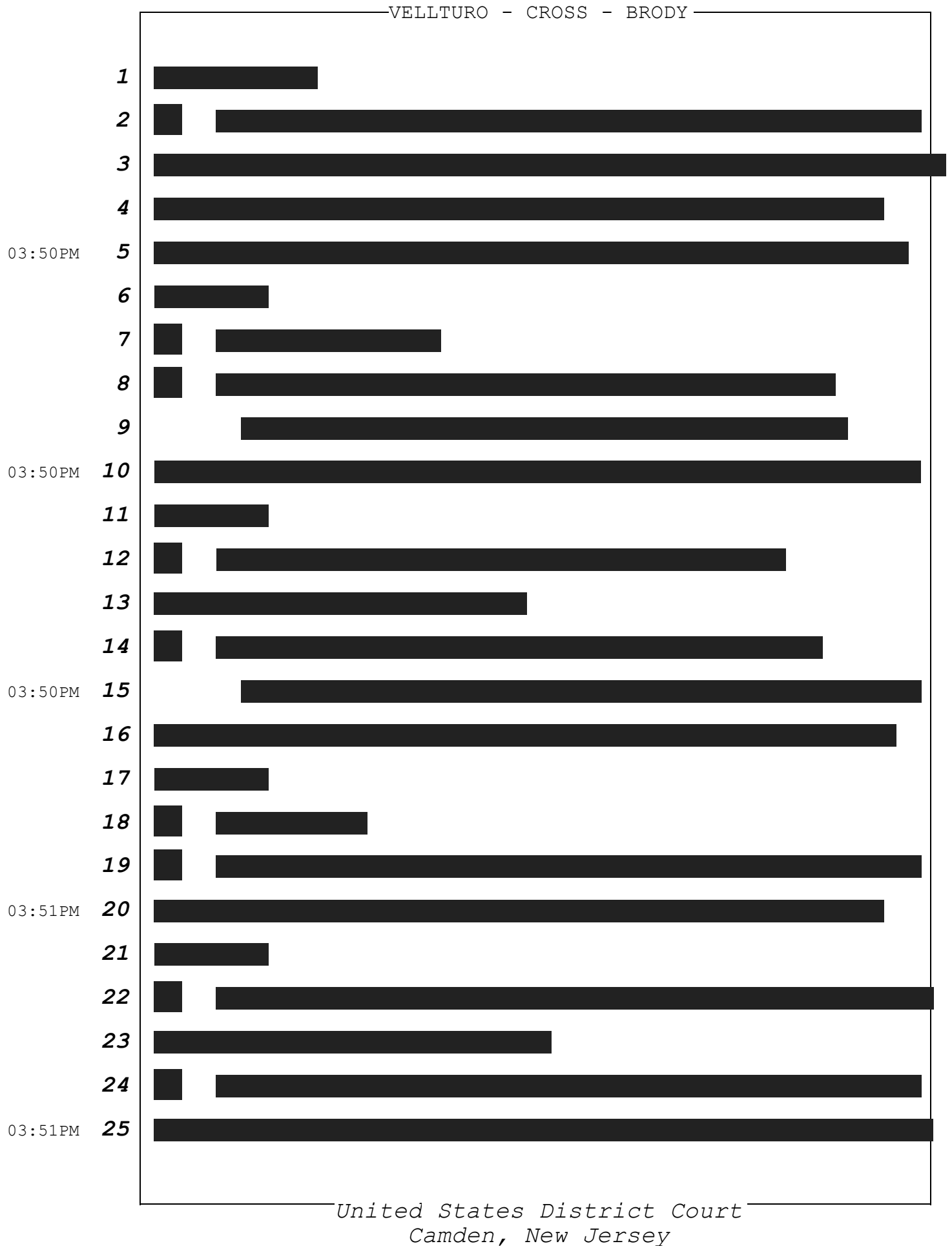


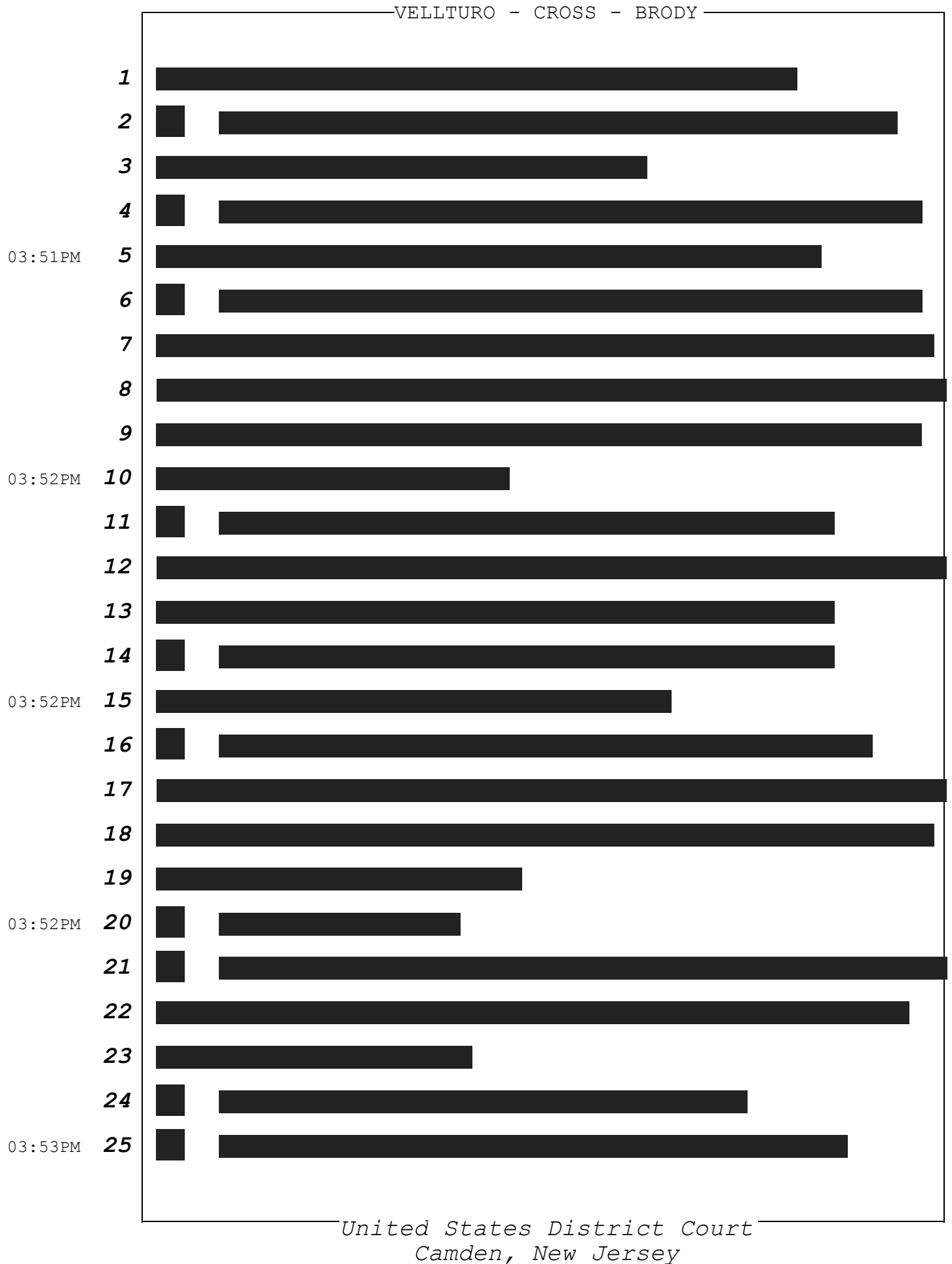
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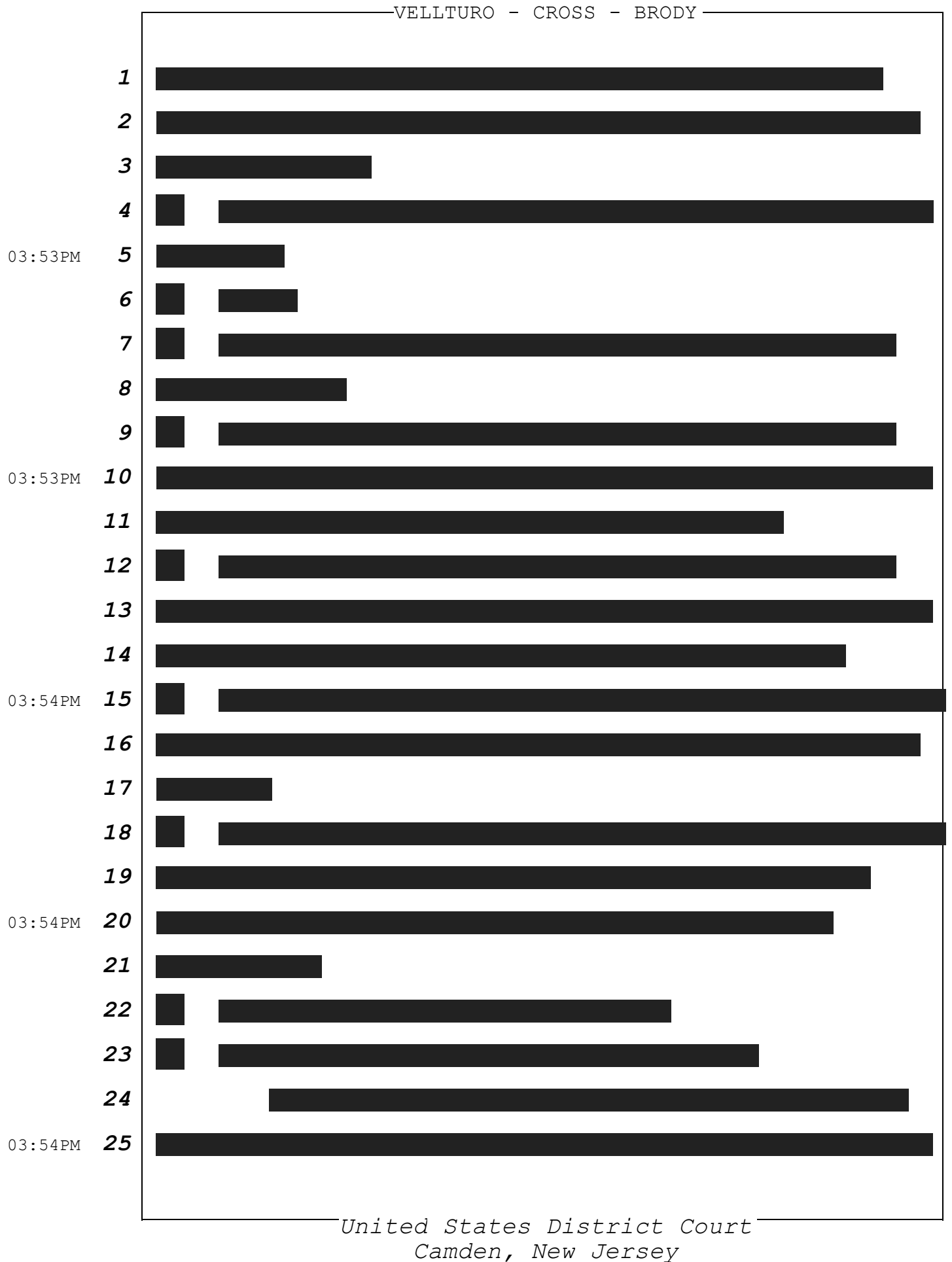
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United States District Court
Camden, New Jersey







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(By order of the court the courtroom was unsealed).

4

Q. Dr. Vellturo, during expert discovery in this proceedings

03:55PM

5

in forming your opinions on irreparable harm you relied on

6

declarations filed with this court during the litigation on

7

behalf of AstraZeneca. Correct?

8

A. Yes.

9

Q. Specifically you opined that AstraZeneca would suffer a

03:55PM

10

variety of irreparable harms as described in declarations by

11

Linda Palczuk, correct?

12

A. Yes, that's one of the declarations.

13

Q. Now, Ms. Palczuk has not testified during these trial

14

proceedings. Correct?

03:55PM

15

A. Correct.

16

Q. And you never relied upon any declaration or written

17

submission by Mr. Hudson on harm issues during the course of

18

this litigation?

19

A. Other than having heard him testify this morning, and I

03:55PM

20

read his deposition from last week.

21

Q. When forming your opinions in this litigation relevant to

22

harm issues, you had never spoken to Mr. Hudson, correct?

23

A. That's correct.

24

Q. For your harm testimony today, are you relying upon any

03:56PM

25

information provided by Ms. Palczuk by way of her declarations

—VELLTURO - CROSS - BRODY—

1 submitted in this case?

2 A. Yes. The two parameters I identified, that is the 3.7
3 percent unit decline and the one percent -- I'm sorry, the
4 3.7 percent annual per unit -- I'm sorry, annual unit decline
03:56PM 5 for BIS collectively, and the one percent price decline, those
6 come from the Palczuk declaration and my conversations with
7 her.

8 Q. Now, it's true that you have calculated the estimated
9 monetary loss AstraZeneca would allegedly incur based on a
03:56PM 10 generic BIS launch by one or more defendants in this
11 litigation, correct?

12 A. I've calculated, right, what I understand to be the pure
13 pecuniary or monetary loss in terms of lost royalties and lost
14 revenues.

03:57PM 15 Q. And you assessed that loss in the context of the
16 scenarios you discussed during your direct exam, correct?

17 A. Yes, I think we've captured all of them.

18 Q. And those scenarios included one covering the period
19 December 2014 to May 2019?

03:57PM 20 A. Yes.

21 Q. And then there was two other scenarios that covered
22 60-day periods, correct?

23 A. That's correct.

24 Q. Now, I want to take a look at your slide PDX- 28.10,
03:57PM 25 please. Here you have estimated AstraZeneca's annual lost

—VELLITURO - CROSS - BRODY—

1 revenue following entry by all defendants of nearly \$300
2 million. Correct?

3 A. Yes.

4 Q. And that number includes reduced royalty and sales
5 revenues, correct?

6 A. That's correct.

7 Q. Now, for the scenario that you show on PDX-28.10, you
8 estimated losses continuing through patent expiration in 2019.
9 Correct?

10 A. Yes. It appears on here as well, but it's also appears
11 on the next exhibit.

12 Q. So over four years out, correct?

13 A. Yes.

14 Q. And that scenario is based upon the assumption that the
15 '834 patent is valid and infringed by defendants and yet no
16 permanent injunction has issued to keep defendants from
17 introducing their products into the U.S. marketplace.
18 Correct?

19 A. It assumes that for -- for whatever reason, the three
20 defendants are allowed to introduce their generic products.

21 Q. Is that even in the face of the '834 patent being
22 invalid -- being found valid and infringed?

23 A. That's one possible scenario, yes.

24 Q. And that scenario also assumes that any appeal process
25 would still resolve any verdict that the '834 patent is valid.

—VELLTIURO - CROSS - BRODY—

1 Correct?

2 A. I'm not really sure what that question means.

3 Q. For your scenario on PDX- 28.10, are you taking into
4 account any appeal of a district court decision that the '834
5 patent is valid and infringed?

03:59PM

6 A. I'm not -- I'm not doing that one way or the other. What
7 I'm doing is I'm identifying the harm that takes place if
8 there is no injunction and the generics are permitted into the
9 marketplace.

03:59PM

10 Q. Based on your experience, do you know how long an average
11 appeal is of a district court decision?

12 A. I -- it depends. It depends on the nature of the appeal.
13 I've seen it a very substantial amount. I've had one recently
14 that the Federal Circuit issued that took two years from the
15 verdict and about 18 months from the official papers being
16 filed.

04:00PM

17 Q. Now, your loss estimates assume Teva will lose its
18 generic market share exactly proportional to any additional
19 generic entrants, correct?

04:00PM

20 A. I don't know what that question means.

21 Q. If additional generic entrants were to enter this market,
22 the scenarios that you've compiled assumed that Teva will lose
23 market share, the same amount of market share as AstraZeneca?

24 A. No, that's not correct. That's not what I do.

04:00PM

25 Q. Is it your opinion that Teva will lose market share from

VELLTIURO - CROSS - BRODY

1 entry of the defendants in this case?

2 A. Yes.

3 Q. And in your opinion this loss of share would occur even
4 though Teva was the first company to launch a generic BIS
04:01PM 5 product, correct?

6 A. Yes.

7 Q. And in your opinion, this loss of share would occur even
8 though Teva has been marketing its product for nearly five
9 years under the license agreement, correct?

04:01PM 10 A. I'm not sure what you mean by marketing. Teva doesn't do
11 very much marketing. It's a generic product, they -- they
12 have contracts and contacts with pharmacies and they supply
13 the product.

14 Q. Let me ask it this way.

04:01PM 15 A. Okay.

16 Q. In your opinion, the loss of share would occur to Teva,
17 even though Teva has been selling its generic BIS product for
18 nearly five years under the license agreement, correct?

19 A. That's correct.

04:01PM 20 Q. I want to take a look at your slide PDX- 28.8. Is it
21 correct that this slide shows historical data based on Teva's
22 marketing of its generic BIS product?

23 A. For a limited time period. These are sales.

24 Q. And if you look at the information you have set out for
04:02PM 25 Teva's generic 0.5 mg strength product, which is in the right

—VELLTURO - CROSS - BRODY—

1 hand side of the chart --

2 A. Yes.

3 Q. -- the generic share of total hit its peak in March '09,
4 correct, at 56-percent?

04:02PM 5 A. During the time period for which data is shown here,
6 obviously the share jumps dramatically -- gee, I don't know
7 what happens in December '09. But in January '09, it blows up
8 to about 85 percent right away. But in this time frame 56 is
9 the highest number.

04:02PM 10 Q. I'm just looking at the historical experience you set
11 forth in your PDX- 28.8. Based on this data, Teva's .5 BIS
12 strength product hit its peak in March '09 of 56 percent?

13 A. Among the months that are shown on this chart, that's
14 correct.

04:03PM 15 Q. So that was approximately five months after the product
16 was launched originally in November 2008, correct?

17 A. Yes, that's five months later.

18 Q. Now, your loss estimate based on a generic BIS launch by
19 any of the defendants assumes there is no lag or no gradual

04:03PM 20 change in market share at the time, correct?

21 A. Right. I assumed that the changes would be fairly
22 dramatic and fairly quick.

23 Q. Now, the changes in the market share when Teva launched
24 were not immediate, correct?

04:03PM 25 A. When they did the truncated launch, that's true, but when

—VELLITURO - CROSS - BRODY—

1 they did the licensed launch it did immediately jump. As I've
2 indicated, as one can see here it's down to 10 and 7 percent
3 in November '09. I don't remember the December data as I sit
4 here, but it would be likely lower than that.

04:04PM

5 And if we go to my other chart where you can see the
6 first quarter of 2010, I believe the number's already back up
7 to the eighties. So it was very dramatic and very complete.

8 Q. And I'm just referring to the historical experiences that
9 were in your PDX- 28.8.

04:04PM

10 A. Right. With respect to the limited launch here, the
11 change manifested itself in prescriptions filled after 4 or
12 5 months. Now, this is down the road pipeline-wise from when
13 the product would have first found its way into the hands of
14 the wholesalers and pharmacies.

04:04PM

15 Q. I want to take a look at your Slide PDX- 28.5, please.
16 Now, with Teva's generic launch, AstraZeneca's market share
17 decreased, correct?

18 A. Yes. I'm sorry. You are referring -- that's true
19 generally, but now we're just focusing on this December 2009
20 relaunch, which is what this relates to?

04:04PM

21 Q. Yes. I'm speaking generally first.

22 A. Yeah, share in market.

23 Q. So you testified in your direct that the market share
24 shifts dramatically upon generic entry. Do you recall that?

04:05PM

25 A. Yes, I do.

—VELLTURO - CROSS - BRODY—

1 Q. And so Teva had launched its product again under the
2 license agreement in 2009, correct?

3 A. Right, relaunched it under the license agreement in I
4 think it's December 15, 2009.

04:05PM 5 Q. So, this is a situation where the brand, here the
6 Pulmicort Respules brand, has already given up a large
7 percentage of market share to a generic, correct?

8 A. I guess I'm not following your question. As I indicated
9 in my direct testimony, with the availability of a generic a
04:05PM 10 large portion of the volume will shift from the branded to the
11 generic product, and that did happen here when Teva relaunched
12 its generic.

13 Q. And that's the point I'm trying to make. That shift
14 happened when Teva launched its generic product, correct?

04:06PM 15 A. To a very substantial degree, that's correct.

16 Q. Now, based on your Slide PDX- 28.5, since the Teva
17 generic BIS launch, AstraZeneca's brand share has been
18 maintained generally between ten and 15 percent since 2010; is
19 that correct?

04:06PM 20 A. Leaving out that shortage period I think that's generally
21 correct, yes.

22 Q. Now, the losses you have estimated focus on lost
23 revenues, correct?

24 A. Yes.

04:06PM 25 Q. You have not estimated lost profits, correct?

—VELLTIURO - CROSS - BRODY—

1 A. Right. As I indicated before, the incremental costs are
2 relatively small, but I didn't compute those.

3 Q. And the calculation of lost profits would require one to
4 subtract AstraZeneca's costs, such as costs of goods sold,
04:07PM 5 from all of AstraZeneca's direct sales, correct?

6 A. From its branded sales? That's correct, yes.

7 Q. Do you know what AstraZeneca's costs of goods sold is?

8 A. Which year would you like?

9 Q. Currently.

04:07PM 10 A. Well, for 2014 I have on DTX-2044, I have
11 2014-year-to-date product sales, I'll use net sales, of
12 \$47 million. And I have total expenses of -- I'm sorry,
13 that's just brand expenses. I'm sorry. I don't have costs of
14 goods on this chart. I thought I did.

04:08PM 15 Q. Now, would you agree that profits are less than revenues?

16 A. I would agree that revenues minus incremental costs equal
17 profits. Sometimes incremental costs are zero, as is the case
18 with the royalty revenues from Teva.

19 Q. Now, you agree that in 2008 the U.S. sales of Pulmicort

04:08PM 20 Respules peaked at \$874 million, correct?

21 A. Branded? Yes.

22 Q. Now, it is your understanding that AstraZeneca's present
23 day forecasts show a decline in the sales of Pulmicort
24 Respules units going forward from 2014, correct?

04:09PM 25 A. Yes.

—VELLTIURO - CROSS - BRODY—

1 Q. And the unit sales would decline by 3.7 percent for
2 overall units of BIS, which include generic plus branded,
3 correct?

4 A. Per year, yes.

04:09PM 5 Q. When I say BIS, do you understand that I mean budesonide
6 inhalation suspension?

7 A. Yes, I do.

8 Q. Now, you have seen AstraZeneca forecasts that show a
9 decline in price for upcoming years, correct?

04:09PM 10 A. A very small one, yes. To be clear, are you asking me
11 with respect to scenarios in which there is no additional
12 generic entry, or more generally?

13 Q. I'm just asking you have you seen forecasts, AstraZeneca
14 forecasts that show a decline in price for upcoming years?

04:09PM 15 A. Yes.

16 Q. And those forecasts that reflect declines in price do not
17 account for generic entry other than by Teva, correct?

18 A. Well, those forecasts assume the maintained presence of a
19 generic Teva product and no others. That's my recollection.

04:10PM 20 Q. So even without any other generic launch by defendants,
21 the assumption is that the price of this product will decline,
22 correct?

23 A. By one percent per year.

24 Q. But there will be a decline, correct?

04:10PM 25 A. Some, yes.

—VELLTIURO - CROSS - BRODY—

1 Q. Now, you didn't include any of the actual forecasts
2 showing a decline in your expert report submitted in this
3 litigation, correct?

4 A. I'm sorry. Can I hear that question again?

04:10PM 5 Q. Sure. You did not include any of those forecasts showing
6 a decline in your expert report submitted in this litigation,
7 correct?

8 A. Well, I included those parameters in my calculations of
9 sales going forward, but I don't have the forecasts themselves
04:10PM 10 in my report, that's true.

11 Q. And you didn't look at any of those forecasts in your
12 direct examination today, did you?

13 A. Those forecasts being internal AstraZeneca forecasts?

14 Q. Yes.

04:11PM 15 A. That's correct, I didn't.

16 Q. And again, just to be clear, the forecasts that show a
17 decline in either sales or price going forward from 2014 are
18 the forecasts I'm referring to, you did not look at those
19 forecasts in your direct examination today, did you?

04:11PM 20 A. That's true.

21 Q. Do you know whether AstraZeneca provided defendants a
22 copy of any of those forecasts that show a decline in the
23 current and upcoming years?

24 A. I don't know one way or the other.

04:11PM 25 Q. And you discussed pharmacy substitution during your

—VELLTIURO - CROSS - BRODY—

1 direct exam. Do you recall that?

2 A. Yes.

3 Q. That substitution you were discussing relates to the
4 substitution of a generic for a branded product, correct?

04:11PM **5** A. At the pharmacy, yes.

6 Q. Okay. And so that substitution for BIS would have
7 occurred when Teva launch its generic BIS product, correct?

8 A. That's correct.

9 Q. Now, you testified earlier about literature, including
04:12PM **10** what literature says about pricing. Do you recall that?

11 A. I do.

12 Q. And would you agree that you've also seen literature that
13 shows branded price goes up after generic entry?

14 A. Under very particular conditions that can happen.

04:12PM **15** Q. But you have seen literature that does show under certain
16 circumstances the branded price will go up after generic
17 entry, correct?

18 A. So the Burndt, B-U-R-N-D-T, paper you are referring to, I
19 do recall that paper as based on very old data and I don't
04:12PM **20** believe it's been updated. But I am familiar with that paper.

21 My experience is, again, it depends on the nature of the
22 generic launch.

23 Q. But there is literature that you've seen that shows
24 branded price goes up after generic entry, correct?

04:13PM **25** A. In some instances it does, that is correct.

—VELLTURO - CROSS - BRODY—

1 Q. Now, when you discussed literature in your direct
2 examination today, including what it says about pricing, you
3 did not identify specifically what literature you were
4 referring to, correct?

04:13PM 5 A. True. I have those in my report, but I didn't have my
6 report handy. And my old dissertation advisor, Ernie Burndt,
7 is one of the central authors of all this literature, so I
8 know his papers are in there, I just don't recall the
9 specifics as I sit here.

04:13PM 10 Q. And do you understand that Watson Laboratories, Inc. is a
11 defendant to this litigation?

12 A. Yes.

13 Q. Do you understand that Watson is a wholly-owned
14 subsidiary of Actavis?

04:13PM 15 A. I seem to recall that, yes.

16 MS. BRODY: And, your Honor, for the record the
17 parties have stipulated concerning the corporate status of
18 both Breath and Watson, including that Watson Laboratories,
19 Inc. is a wholly-owned subsidiary of Actavis. This is
04:14PM 20 supplemental stipulated fact number nine found in the revised
21 pretrial order submitted during these remand proceedings.

22 THE COURT: Thank you.

23 BY MS. BRODY:

04:14PM 24 Q. Dr. Vellturo, could you please turn to DTX-3707 in the
25 binder I provided you?

VELLITURO - CROSS - BRODY

1 A. Yes.

2 Q. This is a press release titled "Watson Pharmaceuticals,
3 Inc. is not Now Actavis, Inc."

4 A. I see that title to this press release, yes.

04:14PM 5 Q. And it's dated January 25, 2013?

6 A. Yes.

7 Q. Looking in the second paragraph of this document under
8 the heading about Actavis, do you see that it states "Actavis
9 is the world's third largest generics prescription drug

04:15PM 10 manufacturer"?

11 A. Yes, essentially.

12 Q. And right under that in the next paragraph it states,
13 "The Company is ranked in the top 3 in 12 global markets, the
14 top 5 in 16 global markets, and in the top 10 in 33 global
04:15PM 15 markets." Correct?

16 A. Essentially. There seems to be an issue with the letter
17 T in a few of these spots, but I'm going to ignore that.

18 Q. Is that what your understanding is?

19 A. Yes.

04:15PM 20 Q. Okay, thank you?

21 So as of 2013 at least, Actavis was the world's third
22 largest generic prescriptions drug manufacturer, correct?

23 A. I'm sorry, the third largest --

24 Q. Generic manufacturer.

04:16PM 25 MR. ANTHONY: Objection. This is hearsay not within

VELLTURO - CROSS - BRODY

1 an exception.

2 THE COURT: Okay.

3 MR. ANTHONY: I don't think a foundation has been
4 laid for this.

04:16PM 5 THE COURT: What's the relevance?

6 MS. BRODY: Your Honor, I just want to -- I can move
7 on. The relevance is there has been suggestion that there
8 will be losses in a certain monetary amount and my question,
9 which is relevant I believe to the injunction analysis, is
04:16PM 10 whether the damages are compensable and whether defendants can
11 pay any damages that might be incurred, and so this is just to
12 establish, and I don't believe there is a dispute --

13 THE COURT: Well, those are all proper questions.
14 You don't need this document to do that.

04:16PM 15 MS. BRODY: Okay. I just wanted to provide further
16 information and documentation to support the point, your
17 Honor. But you are correct, I don't have to use that.

18 THE COURT: Okay.

19 BY MS. BRODY:

04:16PM 20 Q. Dr. Vellturo, will you turn to DTX 3702? Actually, let
21 me back up.

22 Do you understand that Actavis is one of the world's
23 largest generic drug manufacturers?

24 A. I'm familiar with Watson being a significant participant
04:17PM 25 in the United States. Worldwide I'm less certain. So I'm not

VELLTURO - CROSS - BRODY

1 sure.

2 THE COURT: What about Actavis?

3 THE WITNESS: Other than the operations under Actavis
4 that are Watson, I really haven't studied what else roles
04:17PM 5 under that name at this point. So I'm not sure.

6 BY MS. BRODY:

7 Q. Sitting here today, Dr. Vellturo, do you have any reason
8 to believe that Watson would not be able to pay any damages
9 the court may award in this case?

04:17PM 10 A. I haven't studied that issue one way or the other.

11 Q. But sitting here today, you have no evidence that Watson
12 would not be able to pay damages, any damages the court may
13 award in this case, correct?

14 A. Correct. I haven't studied the issue.

04:18PM 15 Q. Can you please turn to DTX-3702 in your binder.

16 This is a document entitled "Actavis Net Revenue
17 increases 59% to \$2.779 Billion in Fourth Quarter 2013.
18 Non-GAAP EPS increases 99% to \$3.17," correct?

19 MR. ANTHONY: Objection. Relevance, your Honor.

04:18PM 20 MS. BRODY: Your Honor, it's just to put into
21 evidence just the financial figures of Actavis further
22 supporting that it could pay --

23 THE COURT: But I don't know that that would be
24 proper through this witness.

04:18PM 25 Is AstraZeneca's position that the defendants lack

VELLTURO - CROSS - BRODY

1 the ability to pay a judgment? Is that one of the arguments
2 that's in dispute?

3 MR. ANTHONY: I'm not aware we've ever made that
4 argument. I know that Dr. Vellturo just said he hasn't opined
04:18PM 5 on that.

6 I have a relevance objection. There is also a
7 hearsay objection. These are not his documents, these are --
8 so those are my two objections.

9 THE COURT: Sustained.

04:19PM 10 BY MS. BRODY:

11 Q. Dr. Vellturo, you mentioned the one milligram BIS product
12 in your direct exam, correct?

13 A. I did.

14 Q. Can you take a look to your slide PDX 28.6.

04:19PM 15 And I believe you mentioned the one mg in connection
16 with this slide, do you remember that?

17 And if it's helpful to you, I think it's pulled up on
18 the screen.

19 A. Yes, I see it there. Thanks.

04:19PM 20 Q. And you would agree that the one mg strength makes up
21 only about five percent of the total BIS market, correct?

22 A. Right. Of all BIS prescriptions, only about five percent
23 are one milligram.

04:20PM 24 Q. And I believe you also commented when looking at this
25 slide that Teva was experiencing shortages.

VELLTURO - CROSS - BRODY

1 Do you recall that?

2 A. Yes.

3 Q. When you mentioned that Teva was experiencing shortages,
4 those shortages occurred back in the 2010 and 2011 time frame,
04:20PM 5 correct?

6 A. That's what I recall.

7 Q. You're not aware currently of Teva experiencing any
8 supply shortages with this BIS -- generic BIS product, are
9 you?

04:20PM 10 A. With respect to BIS products?

11 Q. Correct.

12 A. No. Not with respect to BIS products.

13 MS. BRODY: Your Honor, if I may have one moment?

14 THE COURT: Yes.

04:21PM 15 BY MS. BRODY:

16 Q. Dr. Vellturo, I do actually want to ask you about a
17 couple of the numbers you put on your slides.

18 If you could take a look to PTX 1980, please. And
19 that would have been in your direct exam binder.

04:22PM 20 A. Yes.

21 Q. In this model set forth at PTX 1980, do you assume
22 branded price stays the same upon generic entry?

23 A. Yes, I do.

24 Q. Now, on your slide PDX 28.2 --

04:22PM 25 A. Can I make one slight revision to that? I have a one

VELLTIURO - CROSS - BRODY

1 percent decline that takes place in both models. So there is
2 a decline, but it's the same between the model with the
3 injunction and without the injunction.

4 Q. I want to take a look at your PDX-28.12, if we could.

04:23PM 5 Here you have for the 60-day period with the launch
6 by three defendants an amount of 54.8 million, correct?

7 A. Yes.

8 Q. Now, I want to take a look at your PTX-1984 which is,
9 again, in your direct binder.

04:23PM 10 PTX-1984.

11 Is this the data that supports the \$54.8 million on
12 the slide that we just looked to?

13 A. No, not quite.

14 Q. Okay.

04:23PM 15 A. Some of the parameters are here, but the data
16 calculations are in another exhibit.

17 Q. So the estimated loss that you see on the second to
18 next -- it says \$54.7, that's not the number that should have
19 been on your slide. I'm just trying to make sure I understand
04:24PM 20 whether your numbers are accurate.

21 A. Oh, I'm sorry. This is Exhibit 10? Now we're on exhibit
22 10, not Exhibit 9?

23 Q. Correct.

24 A. I'm sorry. I was looking at Exhibit 9.

04:24PM 25 Q. PTX-1984.

VELLTIURO - CROSS - BRODY

1 I'm trying to determine --

2 A. I'm sorry, we're also on 1984, yes.

3 Q. I'm trying to determine whether the \$54.8 million dollar
4 number on your slide PDX-28.12 is supposed to be supported by
5 the data in PTX-1984?

04:24PM

6 A. It is.

7 Q. Okay. So that PTX-1984 says \$54.7. Is that the number
8 that should have been on your slide PDX-28.12?

9 A. Yes.

04:24PM

10 Q. Okay. And now if you can take a look at -- if we can
11 take a look at PDX-28.13 which is your slide again.

12 This is a 60-day launch by one defendant, correct?

13 A. Correct.

14 Q. And the number you have here is \$40.9 million, correct?

04:25PM

15 A. Correct.

16 Q. Just so I can be clear, is the data that's supposed to
17 support that number, is that your Exhibit 11 which is at PTX
18 1985?

19 A. Yes, it is.

04:25PM

20 Q. Can you take a look at the data on PTX 1985? I want to
21 be sure I understand.

22 In row what's numbered 23 towards the bottom, there
23 is a \$40.9 million dollar number there, correct?

24 A. Correct.

04:25PM

25 Q. Now, that row 23 is computed by taking row three minus

VELLTIURO - CROSS - BRODY

1 row 22, correct?

2 A. Subject to rounding, yes.

3 Q. Well, I'm just looking -- under your sources in the
4 bottom left-hand side of this exhibit, for row 23 you have it
04:26PM 5 equaling three minus 22, correct?

6 A. That's the spread sheet calculation.

7 Q. So if we take row three which is 56.5 minus row 22 which
8 is 15.7, that comes out to \$40.8, correct?

9 A. No, that's not correct. I mean literally your math is
04:26PM 10 correct, but if you look under notes, I have a qualifier that
11 says any difference due to rounding, because just by the sheer
12 way that rounding works, if they get rounded in opposite
13 directions, they'll get rounded to different digits, but then
14 when you subtract them and you're subtracting the full values,
04:26PM 15 you'll get the correct digit. So that's what happened here.

16 THE COURT: Wait. What?

17 It's 40.8. Why are you rounding it to 40.9?

18 THE WITNESS: Well, this is what the spread sheet
19 does. So the actual numbers in the spread sheet --

04:26PM 20 THE COURT: Oh, underlying that?

21 THE WITNESS: Right. Actually go out more decimal
22 points than this. And the mathematical operation is done on
23 the whole number, that is with all the decimal points.

24 THE COURT: Yes. Okay.

04:27PM 25 THE WITNESS: And so sometimes when there is

—VELLTIURO - CROSS - BRODY—

1 differences, they go out beyond the first decimal point. When
2 you do the math, the rounding doesn't quite square up.

3 THE COURT: So it was --

4 THE WITNESS: But the mathematics is correct.

04:27PM 5 THE COURT: Okay. All right.

6 THE WITNESS: If I had a minute, I could do an
7 example.

8 THE COURT: So it's 56 point greater than five. And
9 it's 15 point greater than seven greater than five?

04:27PM 10 THE WITNESS: Right. So it's probably like 56.56.
11 And then the other one is probably 15.67. And so that when
12 you subtract them and round them, you get to \$40.9 instead of
13 \$40.8.

14 THE COURT: Okay.

04:27PM 15 BY MS. BRODY:

16 Q. So based on the numbers that are set forth on your
17 Exhibit 11 which is PTX 1985, the number comes out to 40.8,
18 correct?

04:28PM 19 A. Right. If you use them strictly as reported on single
20 decimal points, that's 40.8, but the underlying calculations
21 in the spread sheets as constructed, the mathematics is
22 correct.

23 Q. And I want to flip back to your PTX 1984 just briefly
24 which is your Exhibit 10.

04:28PM 25 Under the notes, one of the assumptions you make is

VELLTURO - CROSS - GRACEY

1 that Sandoz and Watson entered the generic BIS one mg market,
2 correct?

3 A. Correct.

4 Q. Have you seen any evidence that Watson has approval for
04:28PM 5 the one mg product today?

6 A. I'd have to go back and look at my report. I think that
7 was addressed there. I just don't recall specifically what
8 the basis was for that.

9 Q. Sitting here today do you know?

04:28PM 10 A. I can't remember.

11 MS. BRODY: Your Honor, I have no further questions.

12 THE COURT: Okay.

13 MS. BRODY: Thank you, Dr. Vellturo.

14 THE COURT: Mr. Gracey.

04:29PM 15 (CROSS EXAMINATION OF DR. VELLTURO BY MR. GRACEY:)

16 Q. Just a few.

17 DJ could you pull up DTX 2045.

18 Dr. Vellturo, my name is Taras Gracey, I've not met
19 you yet. I represent Sandoz.

04:29PM 20 A. Hi.

21 Q. I've read a lot of your stuff.

22 I'm sorry, DTX.

23 You recall reviewing this document, correct, doctor?

24 A. Yes, I do.

04:29PM 25 Q. All right. Turn to the second page, page two of six.

—VELLTURO - CROSS - GRACEY—

1 A. Do I have a copy of this document?

2 Q. Yes, you do. It's in your cross-examination binder.

3 I'm sorry.

4 A. And I'm sorry, the exhibit number is what?

04:29PM 5 Q. D, as in David, TX 2045.

6 A. Okay. Thank you.

7 Q. Sure.

8 This is a little bit of a follow-up on what Ms. Brody
9 was just asking you.

04:30PM 10 Now, this is a document generated by AstraZeneca,
11 correct?

12 A. Yes, it is.

13 Q. And it's entitled Teva royalty review, Q1 2014 payment.

14 I want to direct your attention to the last grouping

04:30PM 15 here. As we move into Q2, the Q1 RBU, can you remind U.S.
16 what RBU stands for?

17 A. BU is business unit, so I think royalty business unit.

18 Q. Thank you.

19 The Q1 RBU assumed Teva one mg launch in April. We
04:30PM 20 have not received any notice of FDA approval yet.

21 Do you see that?

22 A. I do.

23 Q. Did you ever have any discussions with anyone inside
24 AstraZeneca about the Teva one mg launch?

04:30PM 25 A. No.

—VELLTIURO - CROSS - GRACEY—

1 Q. Did you ever have any discussions with anyone inside
2 AstraZeneca -- and did you have any conversations with anyone
3 at AstraZeneca about Teva's one mg approval by the FDA?

4 A. No.

04:31PM

5 Q. Did you make any assumptions about a Teva one mg launch
6 in calculating your -- in calculating your figures?

7 A. Yes. I just can't remember as I sit here what that
8 assumption was.

9 It's had such a small affect, I can't remember as I
10 sit here.

04:31PM

11 Q. All right. Well, let's talk a little bit more about
12 Teva.

13 You were asked about the Teva license agreement with
14 AstraZeneca, right?

04:31PM

15 A. Yes.

16 Q. And you've done consulting work for AstraZeneca over the
17 years, is that true?

18 A. No, not other than this case.

19 Q. I actually meant this case.

04:32PM

20 A. Oh, Yes. Over several years.

21 THE COURT: Over the years?

22 THE WITNESS: Over many years, yes.

23 BY MR. GRACEY:

24 Q. When did you first get involved, do you recall?

04:32PM

25 A. In this case?

—VELLTIURO - CROSS - GRACEY—

1 Q. No. For this product.

2 A. I'm sorry. For this product?

3 Q. Yes.

4 A. Sometime in the summer, I believe, of 2008.

04:32PM

5 I was on a plane the Monday morning after

6 Thanksgiving to come here when I heard about this license.

7 Q. Okay. Did you consult with AstraZeneca about the Teva
8 license agreement?

9 A. No. I wouldn't have been on a plane otherwise, if I had
04:32PM 10 known there was a license coming. I had no idea this was
11 being negotiated over that time period.

12 Q. But before it was executed, did you ever consult with
13 AstraZeneca about the Teva license agreement?

14 A. I did not.

04:32PM

15 Q. Have you been involved with consulting with
16 pharmaceutical companies when they negotiate a license
17 agreement?

18 A. Would you include hospitals in that question, to the
19 extent they developed their own drugs and patents?

04:33PM

20 Q. Sure.

21 A. The answer is yes.

22 Q. And is that recent, over the last five, six years or so?

23 A. Yes.

24 Q. And do you know if those agreements got reported to the
04:33PM 25 Federal Trade Commission?

—VELLTIURO - CROSS - GRACEY—

1 A. With respect to a hospital, I don't believe they were.

2 Q. Have you been involved in any scenarios where a generic
3 and a branded enter into a license agreement and that license
4 agreement gets submitted to the FTC for approval?

04:33PM 5 A. Yes.

6 Q. And do you understand what the role of the FTC is in that
7 situation, right? It's to prevent anti-competitive behavior,
8 is that true?

9 A. Yes, technically.

04:34PM 10 Q. Do you think this Teva license agreement would be
11 approved by the FTC today if they knew about it?

12 MR. ANTHONY: Objection, your Honor. Scope.

13 THE COURT: Sustained.

14 MR. GRACEY: Okay. Let me try it a different way.

04:34PM 15 BY MR. GRACEY:

16 Q. You were asked questions about whether the license
17 agreement is even enforceable due to the '099 and '603 patents
18 being invalidated, do you recall that discussion?

19 MR. ANTHONY: Objection.

04:34PM 20 THE COURT: Well --

21 MR. ANTHONY: I don't think the question was whether
22 I -- the witness thinks the agreement is enforceable, but I
23 think the record speaks for itself.

24 THE COURT: Yeah, I don't think he was asked those
04:34PM 25 questions. He was asked about various provisions. I don't

—VELLTIURO - CROSS - GRACEY—

1 think he rendered an opinion whether or not it was enforceable
2 or not.

3 Were you?

4 THE WITNESS: I didn't express an opinion about
04:35PM 5 enforceability. That's not what I do.

6 THE COURT: Okay.

7 BY MR. GRACEY:

8 Q. So let's try it a different way.

9 You had stated that, I believe, that it didn't matter
04:35PM 10 to you, is that fair, that whether this agreement is
11 enforceable or not, it didn't matter to your analysis?

12 A. No, I wouldn't characterize my statements that way at
13 all.

14 Q. How would you characterize it, then?

04:35PM 15 A. The way I did, which is there was a certain state of the
16 world that I needed to understand for the purposes of one of
17 my calculations relative to the other, and with that
18 understanding, I went forward and did my calculations.

19 Q. Right. And so it's not your testimony that if this
04:35PM 20 agreement between Teva and AstraZeneca is found to violate
21 public policy because it's anti-competitive, that wouldn't
22 affect your analysis at all?

23 MR. ANTHONY: Objection, your Honor. This is
24 irrelevant, prejudicial. I think this really takes the trial
04:36PM 25 far afield.

—VELLTIURO - CROSS - GRACEY—

1 THE COURT: Well, I think what Mr. Gracey is asking
2 about is testimony that this witness gave. Let me find it.

3 Can you be more precise, Mr. Gracey?

4 MR. GRACEY: In my question or where --

04:36PM

5 THE COURT: The testimony that was given by this
6 witness. That's what you're asking about, testimony that he
7 gave?

8 MR. GRACEY: Yes.

9 THE COURT: Do you recall the testimony that he gave?

04:37PM

10 BY MR. GRACEY:

11 Q. Yes.

12 I believe you talked about two different worlds,
13 right? The world if there was an injunction, what would
14 happen to sales and profits for AstraZeneca, and if there
15 wasn't an injunction, right?

04:37PM

16 A. Essentially, yes.

17 Q. Okay. And there were some questions that you heard of
18 AstraZeneca's witness about whether the agreement between Teva
19 and AstraZeneca was even enforceable.

04:37PM

20 Do you recall that discussion.

21 MR. ANTHONY: Objection.

22 THE COURT: Yes. At that point, Mr. Gracey, I think
23 I ordered him to be removed from the courtroom. So be careful
24 where you're treading.

04:37PM

25 MR. GRACEY: Okay. I'm only asking about the

—VELLTIURO - CROSS - GRACEY—

1 testimony from AZ's witness. I don't believe he was excluded
2 during any of that testimony, but if I'm wrong, I'll withdraw.

3 MR. ANTHONY: I think the court at one point -- well,
4 the record says what it says. And I think asking whether the
04:38PM 5 parties -- the term "in force" and the term "enforceable" I
6 think are different. And I guess I heard the testimony
7 differently from Mr. Gracey, but the record will speak for
8 itself.

9 MR. GRACEY: Let me try it like this.

04:38PM 10 BY MR. GRACEY:

11 Q. Let me pose you a hypothetical.

12 Let's say, hypothetically, the agreement between Teva
13 and AstraZeneca is found to be -- to violate public policy as
14 being anti-competitive.

04:38PM 15 How does that fact -- and, therefore, the royalty
16 agreement goes away.

17 How does that fact impact your opinions in this case,
18 if at all?

19 A. I'm sorry. The qualifier is, therefore, that agreement
04:38PM 20 goes away?

21 Q. Yes. It's invalid. It's not enforceable. It's gone.

22 A. I have no idea.

23 Q. You have no idea how it would impact your opinions in
24 this case?

04:38PM 25 A. No, I haven't taken that into consideration. I

VELLTURO - REDIRECT - ANTHONY

1 constructed two states of the world and that doesn't factor
2 into one of those states of the world.

3 MR. GRACEY: That's all I have. Pass the witness.

4 THE COURT: Okay.

04:39PM 5 MR. BASILE: No questions, your Honor.

6 THE COURT: Okay. Any redirect, Mr. Anthony?

7 MR. ANTHONY: I do have a very brief redirect.

8 (REDIRECT EXAMINATION OF DR. VELLTURO BY MR. ANTHONY:

04:39PM 9 Q. Dr. Vellturo, you were asked some questions by Ms. Brody
10 about a set of assumptions that there would be, absent entry
11 by the defendants, a decline of something on the order of one
12 percent or so in prices going forward.

13 Do you recall being asked questions about that?

14 A. One percent per year, yes.

04:39PM 15 Q. And I believe I heard you testify that you said you
16 included those parameters in your report.

17 Do you recall testifying to that on cross-examination
18 by Ms. Brody?

04:40PM 19 A. Yes. And it actually should appear on Exhibits nine, ten
20 and 11 that we were just going through.

21 Q. I want to ask you about the source of that information.

04:40PM 22 Did you include the source of that information, not
23 in any of the exhibits that I think that are in front of you,
24 sir, because I don't think it's in front of you, did you
25 include the source of that information in one of your two

VELLTURO - REDIRECT - ANTHONY

1 reports?

2 A. Yes, I did.

3 Q. And in particular in your first of your two reports you
4 filed over the summer, your July 3rd report, did you identify
04:40PM 5 the parameter in that report, to the best you recall?

6 A. Yes, I did.

7 Q. And what I would ask you to do is -- let me ask you this:
8 Sitting here right now, without any memory refreshment, are
9 you able to say exactly what the source was of that

04:40PM 10 information or would you have to refresh your memory by
11 looking at the report?

12 A. My recollection is it came from conversations with and
13 the Palczuk declaration.

14 Might have been the Wojciechowski declaration. It
04:41PM 15 was one of those two.

16 Q. And you just gave a name that I can provide a spelling to
17 the reporters for at the break.

18 But would it help you to look at the report to
19 refresh your recollection of what your source was?

04:41PM 20 A. Sure.

21 MR. ANTHONY: Your Honor, may I approach the witness?

22 THE COURT: Yes.

23 BY MR. ANTHONY:

24 Q. Dr. Vellturo, I've handed you a copy of your report for
04:41PM 25 purposes of refreshment and maybe I can help U.S. all get home

VELLTIURO - REDIRECT - ANTHONY

1 a little sooner if I direct your attention to page 14 and then
2 there is a footnote 45.

3 And I ask you to take a look at the text associated
4 with that footnote and the footnote and then once you're
04:41PM 5 finished looking at it, if you can simply tell the court yes
6 or no whether that refreshes your memory as to the source of
7 that information?

8 A. Yes, it does.

9 Q. And if you can put it aside and with your memory so
04:42PM 10 refreshed, are you able to tell the court what your
11 recollection is of your source for that information?

12 A. Ms. Wojciechowski at that point, yes.

13 Q. Okay. And just for the court reporter's benefit, I
14 believe that's spelled W-O-J-C-I-E-C-H-O-W-S-K-I.

04:42PM 15 And I think it's pronounced Wojciechowski. But in
16 any event, is that the source of your information?

17 A. It is.

18 MR. ANTHONY: Okay. I have no further questions.

19 THE COURT: Okay. Anything on that?

04:42PM 20 MS. BRODY: No, nothing further, your Honor.

21 MR. GRACEY: Nothing, your Honor.

22 THE COURT: Okay. You're excused.

23 THE WITNESS: Thank you, your Honor.

24 THE COURT: You can go home.

04:43PM 25 Okay. It's been a long day and I'll see you all

VELLTURO - REDIRECT - ANTHONY

1 tomorrow.

2 Tomorrow who is on deck?

3 MS. BRODY: Your Honor, Breath and Watson defendants
4 will be presenting Dr. Philip Nelson and that will be the only
04:43PM 5 witness tomorrow.

6 THE COURT: Would it okay to start at 9:30 then?

7 MR. ANTHONY: It's fine with AstraZeneca.

8 THE COURT: Is the witness here? 9:30, okay?

9 Dr. Nelson: Yes. Fine.

04:43PM 10 THE COURT: I promise to get you home tomorrow.

11 So we'll start at 9:30.

12 Okay. Have a good evening.

13 (Adjournment)

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